Rapid diagnostic tests for diagnosing uncomplicated *P. falciparum* malaria in endemic countries (Review)

Abba K, Deeks JJ, Olliaro PL, Naing CM, Jackson SM, Takwoingi Y, Donegan S, Garner P

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[Diagnostic Test Accuracy Review]

Rapid diagnostic tests for diagnosing uncomplicated *P. falciparum* malaria in endemic countries

Katharine Abba[1], Jonathan J Deeks[2], Piero L Olliaro[3], Cho-Min Naing[4], Sally M Jackson[1], Yemisi Takwoingi[2], Sarah Donegan[1], Paul Garner[1]

[1]International Health Group, Liverpool School of Tropical Medicine, Liverpool, UK. [2]Public Health, Epidemiology and Biostatistics, University of Birmingham, Birmingham, UK. [3]UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases (TDR), World Health Organization, Geneva, Switzerland. [4]Division of Community Medicine, International Medical University, Kuala Lumpur, Malaysia

Contact address: Katharine Abba, International Health Group, Liverpool School of Tropical Medicine, Pembroke Place, Liverpool, Merseyside, L3 5QA, UK. K.abba@liverpool.ac.uk.

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ABSTRACT

Background

Rapid diagnostic tests (RDTs) for *Plasmodium falciparum* malaria use antibodies to detect either HRP-2 antigen or pLDH antigen, and can improve access to diagnostics in developing countries.

Objectives

To assess the diagnostic accuracy of RDTs for detecting *P. falciparum* parasitaemia in persons living in endemic areas who present to ambulatory healthcare facilities with symptoms suggestive of malaria by type and brand.

Search strategy

We undertook a comprehensive search of the following databases: Cochrane Infectious Diseases Group Specialized Register; MEDLINE; EMBASE; MEDION; Science Citation Index; Web of Knowledge; African Index Medicus; LILACS; IndMED; to January 14, 2010.

Selection criteria

Studies comparing RDTs with a reference standard (microscopy or polymerase chain reaction) in blood samples from a random or consecutive series of patients attending ambulatory health facilities with symptoms suggestive of malaria in *P. falciparum* endemic areas.

Data collection and analysis

For each study, a standard set of data was extracted independently by two authors, using a tailored data extraction form. Comparisons were grouped hierarchically by target antigen, and type and brand of RDT, and combined in meta-analysis where appropriate.

Main results

We identified 74 unique studies as eligible for this review and categorized them according to the antigens they detected. Types 1 to 3 include HRP-2 (from *P. falciparum)* either by itself or with other antigens. Types 4 and 5 included pLDH (from *P. falciparum)* either by itself or with other antigens. In comparisons with microscopy, we identified 71 evaluations of Type 1 tests, eight evaluations of Type 2 tests and five evaluations of Type 3 tests. In meta-analyses, average sensitivities and specificities (95% CI) were 94.8% (93.1% to 96.1%) and 95.2% (93.2% to 96.7%) for Type 1 tests, 96.0% (94.0% to 97.3%) and 95.3% (87.3% to 98.3%) for Type 2 tests, and 99.5% (71.0% to 100.0%) and 90.6% (80.5% to 95.7%) for Type 3 tests, respectively.

Overall for HRP-2, the meta-analytical average sensitivity and specificity (95% CI) were 95.0% (93.5% to 96.2%) and 95.2% (93.4% to 99.4%), respectively.

For pLDH antibody-based RDTs verified with microscopy, we identified 17 evaluations of Type 4 RDTs and three evaluations of Type 5 RDTs. In meta-analyses, average sensitivity for Type 4 tests was 91.5% (84.7% to 95.3%) and average specificity was 98.7% (96.9% to 99.5%). For Type 5 tests, average sensitivity was 98.4% (95.1% to 99.5%) and average specificity was 97.5% (93.5% to 99.1%).

Overall for pLDH, the meta-analytical average sensitivity and specificity (95% CI) were 93.2% (88.0% to 96.2%) and 98.5% (96.7% to 99.4%), respectively.

For both categories of test, there was substantial heterogeneity in study results. Quality of the microscopy reference standard could only be assessed in 40% of studies due to inadequate reporting, but results did not seem to be influenced by the reporting quality.

Overall, HRP-2 antibody-based tests (such as the Type 1 tests) tended to be more sensitive and were significantly less specific than pLDH-based tests (such as the Type 4 tests). If the point estimates for Type 1 and Type 4 tests are applied to a hypothetical cohort of 1000 patients where 30% of those presenting with symptoms have *P. falciparum*, Type 1 tests will miss 16 cases, and Type 4 tests will miss 26 cases. The number of people wrongly diagnosed with *P. falciparum* would be 34 with Type 1 tests, and nine with Type 4 tests.

Authors' conclusions

The sensitivity and specificity of all RDTs is such that they can replace or extend the access of diagnostic services for uncomplicated *P. falciparum* malaria. HRP-2 antibody types may be more sensitive but are less specific than pLDH antibody-based tests, but the differences are small. The HRP-2 antigen persists even after effective treatment and so is not useful for detecting treatment failures.

BACKGROUND

Target condition being diagnosed

Malaria is a life-threatening illness, caused by the asexual form of the parasitic protozoan *Plasmodium.* Most cases of malaria are uncomplicated, commonly presenting with fever and sometimes with other non-specific symptoms including headache, and aches and pains elsewhere in the body (Gilles 1991; WHO 2003). A few people develop severe malaria, with confusion, weakness, coma and other life-threatening complications. Malaria is curable, and early, prompt and accurate diagnosis followed by appropriate treatment helps to reduce illness and death, (WHO 2003) and is central to current malaria control policy (Bell 2006; WHO 2005).

The two most common species of malaria parasite are *Plasmodium falciparum* and *Plasmodium vivax. P. falciparum* malaria is by far the most common type of malaria in Africa, and is also endemic in parts of Asia and South America. It is the most common cause of severe malaria, is responsible for almost all malaria deaths, and can cause other complications such as anaemia and, in pregnancy, low birth-weight babies. *Vivax* malaria is a relapsing form, which is rarely fatal but can cause serious anaemia in children. Less common human malaria parasite species include *P. malariae* and *P. ovale.*

In 2008, there were between 190 million and 311 million cases of malaria worldwide (WHO 2009a). Around 85% of these cases were in Africa; 10% were in South East Asia; 4% were in the Eastern Mediterranean region; and 1% were in South America (WHO 2009a). In the same year, there were between 708,000 and 1,003,000 deaths from malaria; 89% were in Africa and 85% were children under the age of five years (WHO 2009a).

People who are repeatedly exposed to malaria infection develop a partial and incomplete immunity. In highly endemic areas, those most at risk are children under the age of five, who have not yet had the chance to develop immunity. In less endemic areas, or areas of seasonal or epidemic transmission, older children and adults are also at risk due to less developed immunity. Travellers from non-endemic to endemic countries are at highest risk because they have no immunity at all.

Index test(s)

Rapid diagnostic tests (RDTs) (WHO 2003) detect parasite-specific antigens in a drop of fresh blood through lateral flow immunochromatography (WHO 2006). The World Health Organization (WHO) currently lists 96 commercially-available test kits meeting ISO13485:2003 manufacturing standards (WHO 2009). RDTs do not require a laboratory or any special equipment (WHO 2006); they are simple to use and can give results as a simple positive/ negative result, within 15 minutes (Talman 2007). RDTs are therefore, in general, suitable for remote areas with limited facilities and relatively untrained staff. However, they have a limited shelf life, and need to be kept dry and away from extremes of temperature. They may also fail to detect malaria in cases where there are low levels of parasites in the blood, and false positives are possible due to cross reactions or gametocytaemia (infection with the sexual stage of the parasite only) (Kakkilaya 2003).

RDTs use antibodies to detect one or several antigens. The most commonly used antibodies react to histidine-rich protein-2 (HRP-2), aldolase and plasmodium lactate dehydrogenase (pLDH) (Talman 2007). HRP-2 is a marker for *P. falciparum*, while pLDH antibodies can be specific for *P. falciparum,* or *P. vivax,* or may detect all species (including *P. ovale* and *P. gambiae*) or other combinations of these species. Aldolase antibodies are pan-specific, detecting all types of malaria parasite but not differentiating between them. Until recently, there were seven main types of commercially-available test, using different antigen combinations as described in Table 1 below (Bell 2006).

Table 1. Types of malaria RDTs by antibody combination and parasite species detected

Type of Test	Antibody Combinations	Possible Results
Type 1	HRP-2 (*P. falciparum* specific)	No Pf; Pf; invalid
Type 2	HRP-2 (*P. falciparum* specific) and aldolase (pan-specific)	No malaria; Pf or mixed; Pv, Pf and/or Pm; invalid
Type 3	HRP-2 (*P. falciparum* specific) and pLDH (pan-specific)	No malaria; Pf or mixed; Pv, Pf and/or Pm; invalid
Type 4	pLDH (*P. falciparum* specific) and pLDH (pan-specific)	No malaria; Pf or mixed; Pv, Pf and/or Pm; invalid
Type 5	pLDH (*P. falciparum* specific) and pLDH (*P. vivax*-specific)	No malaria; Pf; Pv; Pf and Pv; invalid

Table 1. Types of malaria RDTs by antibody combination and parasite species detected (*Continued*)

Type 6	HRP-2 (*P. falciparum* specific), pLDH (pan-specific) and pLDH (*P. vivax* specific)	No malaria; Pf and Pv =/- Po and/or Pm; Pf +/- Po and/or Pm; Pv +/- Po and/or Pm; Po and/or Pm; invalid
Type 7	Aldolase (pan-specific)	No malaria; Pf, Pv, Po and/or Pm; invalid

Pf *P. falciparum;* Pv *P. vivax;* Pm *P. malariae*; Po *P .ovale*

Since this classification was developed, the following test types have also become available.

- Pan pLDH antibodies only, with the following possible results: no malaria; *P. falciparum*, *P. vivax*, *P. ovale* and/or *P. malariae*; and invalid (as for Type 7 tests).
- *P. vivax*-specific pLDH antibodies only.
- pLDH antibody lines detecting *P. vivax*, *P. ovale* and *P. malariae* in combination.

The different test types detect different malaria species and combinations of species; the choice of RDT used will therefore depend on which species are endemic in the area. Table 2 shows the type of tests that are appropriate for use in the different malaria 'zones' of the world.

Table 2. Malaria 'zones' by endemic parasite species and RDT type appropriate for each

Zone	Endemic malaria parasites	Geographic area	Appropriate test type
1	*P. falciparum* only or other species almost always as a mixed infection	Most of sub-Saharan Africa; lowland Papua New Guinea	Tests using HRP-2 to detect *P. falciparum* only (Type 1)
2	Both *P. falciparum* and *P. vivax*, most commonly as a single species	Asia and the Americas; Ethiopian highlands	Combination RDTs which detect all species and distinguish between *P. falciparum* and *P. vivax* (Types 2 to 6)
3	Non-*falciparum* only	*Vivax* only areas of East Asia and Central Asia; some highland areas elsewhere	Pan-specific or *vivax*-specific RDTs (Type 7; Pan-pLDH only; *vivax*-pLDH only)

HRP-2 can stay in the blood for up to 28 days after starting antimalarial therapy (Kakkilaya 2003). Because of this 'persistent antigenaemia', it is not possible to use these tests for assessing parasite clearance following treatment, and false positive results may be found in patients who have recently been treated for malaria. In contrast, pLDH is rapidly cleared from the blood following parasite death; in fact, it may clear more rapidly than the dead parasites (WHO 2009), but may persist in the presence of gametocytes.

Reference tests

Microscopic examination of Giemsa-stained thick and thin blood films remains the conventional laboratory method for malaria diagnosis, but needs to be conducted by microscopists with ade-

quate training and equipment. Microscopic examination displays a good sensitivity and specificity, and allows species and stage differentiations and quantification of parasites, all of which are important in assessing the disease severity and prescribing appropriate therapy. Intensive examination is more likely to reveal parasitaemia, so the test is carried out by examining a fixed number of fields; infections may be missed if slides are not examined carefully (Wongsrichalanai 2007). Very low parasitaemia may be missed even by good quality microscopy; the limit of detection of thick smear microscopy has been estimated at between around four and 20 asexual parasites per μl, although under field conditions a threshold of between 50 and 100 asexual parasites per μl is more realistic (Wongsrichalanai 2007). On the whole, false positive results are the result of poor slide preparation or reading (Wongsrichalanai 2007).

Molecular DNA amplification via polymerase chain reaction (PCR) is the most accurate method of detecting parasites in the blood. It eliminates observer error and is more sensitive at low levels of parasitaemia, with limits of detection as low as 0.004 asexual parasites per μl (Hanscheid 2002; Snounou 1993). However, whether this increased ability to detect low level parasitaemias makes it a better diagnostic test is uncertain, as sub-microscopic parasitaemias are of unknown clinical significance and the prevalence of asymptomatic sub-microscopic infection is high in some areas (May 1999). In addition, PCR may be prone to false positive results due to contamination of samples if laboratory standards are not sufficiently high. PCR is currently not widely available outside of research settings, as it needs specially-trained technicians and a well-equipped laboratory.

Alternative test(s)

Microscopic examination of Giemsa-stained thick and thin blood films remains the conventional laboratory method for malaria diagnosis and is the gold standard, but needs to be conducted by microscopists with adequate training and equipment. Microscopic examination displays a good sensitivity and specificity, and allows species and stage differentiations and quantification of parasites, all of which are important in assessing the disease severity and prescribing appropriate therapy. Intensive examination is more likely to reveal parasitaemia so the test is carried out by examining a fixed number of fields; infections may be missed if slides are not examined carefully (Wongsrichalanai 2007). Very low parasitaemia may be missed even by good quality microscopy; the limit of detection of thick smear microscopy has been estimated at between four and 20 asexual parasites per μl, although under field conditions a threshold of between 50 and 100 asexual parasites per μl is more realistic (Wongsrichalanai 2007). On the whole, false positive results are the result of poor slide preparation or reading (Wongsrichalanai 2007).

Rationale

Diagnostic tests for malaria in endemic areas are now recommended as routine by the WHO in all patients suspected of malaria before any treatment begins (WHO 2010). This is due to a shift in drug treatment policy away from cheap, often relatively ineffective, drugs, towards artemisinin-based combination treatment (ACTs), which are highly effective, expensive, and need to be used properly to prevent resistance developing.

There is a long-standing recognition that good quality, standard malaria microscopy is relatively expensive and difficult to deliver in many basic, primary health care settings in developing countries, while RDTs for malaria have now become widely available and affordable.

RDTs in malaria could dramatically increase access to prompt diagnosis in primary health care. The question of how a package of care (diagnosis using RDTs with positive cases treated with drugs versus presumptive treatment of all cases with symptoms suggestive of malaria) impacts on health outcomes is to be addressed in a separate forthcoming review (Odaga 2011). However, important policy questions remain to be answered

a) How well do RDTs perform compared to the previous standard of microscopy in diagnosing symptomatic patients?

b) What are the differences in accuracy between different types of commercial test, and individual brands of commercial tests?

This information will help to inform choice, although factors, such as price, product consistency, stability and shelf life will also influence those decisions.

This review is the first of a series of three reviews: the second will examine the accuracy of RDTs for diagnosing uncomplicated *P. vivax* and other non-*falciparum* malaria; and the third will assess trials that incorporate RDTs into treatment protocols (Odaga 2011). Previous published reviews have examined travellers only (Marx 2005) or just one particular test (Cruciani 2004).

OBJECTIVES

To assess the diagnostic accuracy of RDTs for detecting clinical *P. falciparum* malaria (symptoms suggestive of malaria plus *P. falciparum* parasitaemia detectable by microscopy) in persons living in malaria endemic areas who present to ambulatory healthcare facilities with symptoms of malaria, and to identify which types and brands of commercial test best detect clinical *P. falciparum* malaria.

Investigation of sources of heterogeneity

We planned to investigate heterogeneity in relation to the index test (by commercial test, test type and grouped by HRP-2/pLDH) and reference tests (microscopy vs PCR), as well as the study par-

ticipants' age, endemicity of malaria, and geographic area (by continent).

METHODS

Criteria for considering studies for this review

Types of studies

Studies evaluating one or more RDTs in a consecutive series of patients, or a randomly-selected series of patients, were eligible. Where the report did not explicitly state that sampling was consecutive, but consecutive sampling was judged most probable, the study was included. Studies were excluded if they did not present sufficient data to allow us to extract or calculate absolute numbers of true positives, false positives, false negatives, and true negatives. Studies were also excluded if they were not available in English, or if they presented insufficient information to fully assess their eligibility.

Participants

Studies recruiting people living in *P. falciparum* malaria endemic areas who attended ambulatory healthcare settings with symptoms of uncomplicated malaria. This included patients attending malaria clinics with self-assessed symptoms.

We excluded studies if participants:

1. were non-immune persons returning from endemic countries or were mainly recent migrant or displaced populations from non-endemic or very low endemicity areas;
2. had been treated for malaria and the test was performed to assess treatment outcome;
3. had symptoms suggestive of severe malaria;
4. did not have symptoms suggestive of malaria;
5. were recruited through active case finding (for example, door-to-door surveys).

In studies with broader inclusion criteria but which presented results stratified by subgroups, we included the data relevant to our inclusion criteria. If studies included some participants with severe malaria, and data specific to a subgroup of participants with uncomplicated malaria could not be extracted, the study was included if 90% or more of the participants had uncomplicated malaria.

Index tests

Studies evaluating any immunochromatography-based RDTs specifically designed to detect *P. falciparum* malaria.

Commerical tests no longer available were included because they may use the same antibodies, and very similar technology, to tests that are currently available or may become available in the future. Older and more recently available versions of the same test, and tests available in both dipstick and cassette format, were included separately. Late prototype tests corresponding to one of the commercially-available types were also included.

Comparator tests

Studies were included regardless of whether they made comparisons with other RDT tests.

Target conditions

Studies aimed to detect *P. falciparum* malaria parasitaemia. Studies that presented RDT results relating only to all types of malaria without distinction by species, but where over 98% of malaria infections by reference standard were associated with *P. falciparum,* were included in this review and analysed as for *P. falciparum*.

Reference standards

Studies were required to diagnose *P. falciparum* malaria using at least one of the following two reference standards.

1. Conventional microscopy of thick blood smears, thin blood smears or both. Presence of asexual *P. falciparum* parasites of any density was regarded as a positive smear.
2. PCR test.

We required that the reference standard was carried out on blood samples taken at the same time and from the same person as the index tests. Where studies used more than one reference standard, we presented data relating to comparisons with each.

Search methods for identification of studies

We used a single search strategy for all reviews in the series.

Electronic searches

To identify all relevant studies, we searched the following databases using the search terms and strategy identified in Appendix 1. The date of the last search was 14 January 2010.

Cochrane Infectious Diseases Group Specialized Register; MEDLINE; EMBASE; MEDION; Science Citation Index; Web of Knowledge; African Index Medicus; LILACS; IndMED. We used the following MeSH, full text and keyword terms: malaria, Plasmodium, reagent kits, diagnosis, diagnostics, RDT, dipstick, MRDD, OptiMal, Binax Now, Parasight, Immumochromatography, antigen detection, antigen test, Combo card. We restricted the searches to human studies. We did not limit the search by language or publication status.

Data collection and analysis

Selection of studies

A single selection procedure was initially used to identify studies for inclusion in either of the two diagnostic test accuracy reviews in the series. The inclusion criteria between the reviews differed only in the target condition and parasite species. Parasite species was therefore the last aspect of the study characteristics to be assessed. One author (KA) initially assessed the titles identified by the search, excluding those obviously irrelevant to the diagnosis of malaria using RDTs.

Letters, review articles, and articles clearly irrelevant based on examination of the abstract and other notes were next excluded and the eligibility of the remaining potentially relevant articles was judged on full text publications independently by two authors (KA SJ) using a proforma. These excluded studies are listed in Characteristics of excluded studies. Any discrepancy was resolved by discussion. Where agreement could not be reached, we consulted a third author (PG or PO). Where it remained unclear whether a study was eligible for inclusion, it was excluded, and we excluded study reports in non-English language reports for logistical reasons.

Studies were named according to the surname of their first author and the year of publication. The study naming used in this review uniquely identifies multiple study cohorts from within each study report (for example as 'Bell 2001a' and 'Bell 2001b'), each of which use different reference standards or present data separately for more than one population with different characteristics. A slightly different notation (for example, 'Singh 1997(a)' and 'Singh 1997(b)') was used to refer to completely separate studies published by an author of the same name in the same year. Note that more that one RDT may be evaluated in each study cohort, thus the number of test evaluations exceeds the number of study cohorts, which exceeds the number of study reports.

Data extraction and management

A standard set of data was extracted from each study cohort, using a tailored data extraction form. Two authors from a pool of three (KA SJ CMN) independently extracted data, and any discrepancies were resolved by discussion. In cases of studies where only a subgroup of participants met the review inclusion criteria, data was extracted and presented only for that particular subgroup. Where two versions of one reference standard or index test were used, for example local clinic and expert standard microscopy or field versus laboratory testing, only the one most likely to yield the highest quality results was included in the review.

For each study, we systematically extracted data on the characteristics of the study, as shown in Appendix 2.

For each comparison of index test with reference test, data were extracted on the number of true positives, true negatives, false positives and false negatives in the form of a two by two table. RDT results are dichotomous; microscopy results were deemed positive at any level of asexual *P. falciparum* parasitaemia; and PCR results used the cut-off points presented by the study authors. Gametocyte-only parasitaemia was considered negative; where a study was unclear on how they had classed gametocyte-only parasitaemia, they were assumed to have used the same classification as ourselves and the data were included in the study. In cases of minor disagreement (within 2%) between two by two table data presented in a study report and reported study sample sizes or calculated accuracies, the data in the table were taken as correct. In cases where there was a large discrepancy, the data were not included in the review.

Data were extracted (Smidt 2008) using current manufacturers' instructions in interpreting the RDT results. *P. falciparum* only and *P. falciparum* as part of a mixed infection were not distinguished and were classed as positive. Non-*falciparum* malaria only was classed as negative for this review. Where study authors interpreted test results or presented data differently, we used all the information presented in the paper to extract data consistent with our own methods; if we were unable to do this, we did not include the data in the analyses.

Reference standard positive was defined as '*P. falciparum* or mixed infection' and reference standard negative as 'no malaria parasitaemia or non-falciparum malaria parasitaemia only'.

Assessment of methodological quality

Two authors from a pool of three (KA SJ CMN) independently assessed the quality of each individual study using the checklist adapted from the QUADAS tool (Whiting 2003). Each question on the checklist was answered with a yes/no response, or noted as unclear if insufficient information was reported to allow a judgement to be made, and the reasons for the judgement made were documented. The criteria used are summarized in Appendix 3.

Statistical analysis and data synthesis

The comparisons made in this review can be considered in a hierarchy. The highest level comparison groups tests by antibody type (HRP-2 versus pLDH) and is formed by combining the test types into two groups: HRP-2 antibody-based (Types 1, 2, 3 and 6) and pLDH antibody-based (Types 4 and 5). However, the data on each test type is classified in the primary studies according to commercial brands. In order to provide a coherent description of the studies contributing to each analysis, the results are structured first by grouping studies according to their commercial brand, then grouping brands to form test types, and finally grouping test types by antibody.

The analytical strategy thus compared the test accuracy of commercial brands within each test type before making comparisons between test types, and then between antibodies. Comparative

analyses first included all studies with relevant data, and were then restricted to studies that made direct comparisons between tests with the same participants, where such studies existed.

For each test type, we plotted estimates of the observed sensitivities and specificities in forest plots and in receiver-operating characteristic (ROC) space. These plots demonstrate the variation in accuracy between studies.

Meta-analyses were undertaken where adequate data were available. Hierarchical summary ROC models (HSROC) that included a random-effects term for variation in accuracy and threshold between studies, and non-symmetrical underlying ROC curves, were fitted. The average operating point for each test was identified on each curve, and average sensitivities and specificities computed. Comparisons between tests were made by adding a covariate for brand, test type or antigen to the accuracy and threshold parameters, assuming a common underlying shape. The impact of test type and antibody on the variability of random-effects of accuracy and thresholds was also investigated and separate variance terms included where required. The significance of the difference in test performance was assessed by a likelihood ratio test comparing models with and without covariate terms for accuracy and threshold. Where inadequate studies were available to estimate all parameters, the HSROC model was simplified by assuming a symmetrical shape to the summary ROC curve or fixed-effect estimates.

Where more than one commercial test of the same type was tested on the same patients against the same reference standard, we selected one type at random from the analysis by test type, in order to avoid bias due to inclusion of the same participants more than once in the analysis. We included both types in any analyses comparing commercial brands.

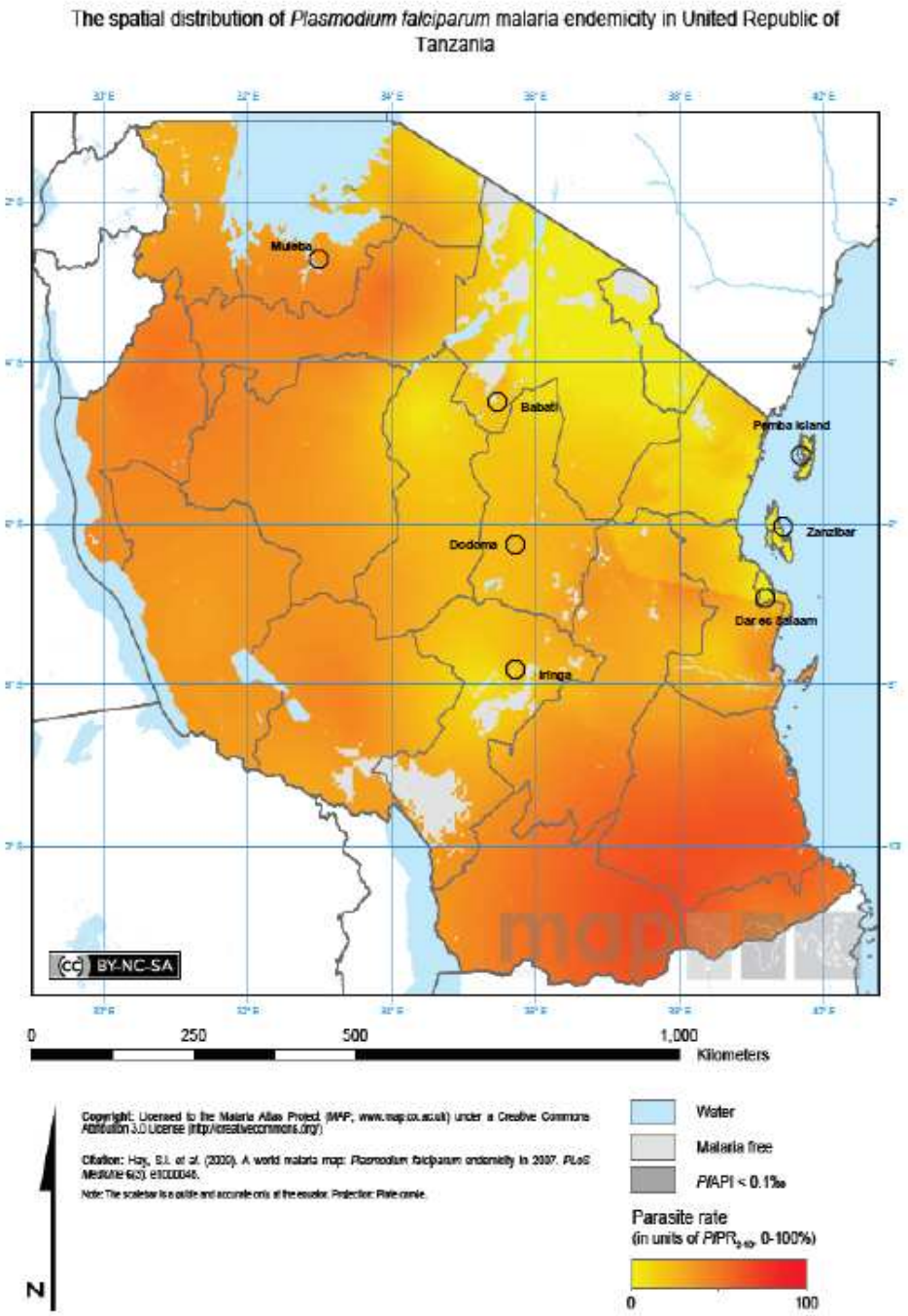
Investigations of heterogeneity

We investigated heterogeneity for Type 1 tests because this was the only test category for which there were sufficient studies available. We investigated variation in sensitivity and specificity by adding to the meta-analysis models covariates indicating the following characteristics: age group; *P. falciparum* endemicity; continent where the study took place; and adequacy of the reference standard.

Age group was classified as: children only; adults only; mixed adults and children; and 'not stated'. Studies including, for example, all ages over the age of five years were classified as 'mixed adults and children'. The age cut-off between adults and children was as used by the study authors.

Endemicity was divided into two categories: high and low. We classified endemicity as 'high' if described by the authors as 'holoendemic', 'hyperendemic' or 'high'; and 'low' if described as 'hypoendemic', 'mesoendemic', 'low' or 'epidemic-prone'. In the case of studies where a reported endemicity was not available, we imputed endemicity using geographical location information provided in the report. This involved mapping the location using 'Google Earth' onto country maps of mean parasite rate in children aged two to ten years in 2007 (Hay 2009) provided by the Malaria Atlas Project (www.map.ox.ac.uk). An example map produced during this process is shown in Figure 1. Study sites with a mean parasite rate of less than 50% were classified as 'low' endemicity to correspond with endemicities of hypoendemic and mesoendemic; study sites with a mean parasite rate of 50% and above were classified as 'high' (Hay 2008). Where the endemicity was unclear and borderline between 'high' and 'low' we assigned it 'high'. Where multiple sites of differing endemicity class were included, and separate results by site were not available, the endemicity assigned to that study was 'mixed'.

Figure 1. Example map showing *P. falciparum* malaria endemicities and study locations



For continent classification, where multi-site studies were conducted across continents and results were not available for different sites separately, the location of the study was classified according to the continent with the largest number of participants.

Sensitivity analyses

Sensitivity analyses were undertaken to investigate the impact of the reference standard method (PCR and PCR-adjusted microscopy) on the results obtained by microscopy alone.

RESULTS

Results of the search

The search identified 3971 titles, of which 3418 were excluded on the basis of title alone. A further 168 were excluded without obtaining full-text articles; 29 were excluded because they were letters; and 139 were excluded on the basis of their abstract. We were unable to obtain one article in full-text form. Full-text articles were retrieved for 384 titles, of which 307 were excluded: 254 because they were initially assessed as ineligible; 17 because the reports did not present sufficient detail for us to be sure of their eligibility or ineligibility; 18 because they were available only in non-English languages; 12 because we were unable to extract absolute numbers of true positives, false positives, false negatives and true negatives; and six because they did not present data on *P. falciparum* malaria, although they were eligible for other reviews in this series.

Two further studies were included as they were identified as eligible during an earlier, scoping stage of the review process but were not identified by the final search.

A total of 74 unique studies described in 79 study reports are therefore included in the review. However, as some of these studies were divided for the purposes of the review (for example, because they used two different reference standards or were conducted in two communities with differing characteristics), 89 separate study cohorts are identified. Fourteen of the 89 study cohorts evaluated more than one test: one compared seven tests, three compared three tests and ten compared two tests. Thus, there are a total of 111 test evaluations reporting a total of 60,396 test results. Microscopy was the reference standard for 104 test evaluations, PCR-adjusted microscopy for two and PCR alone for five,

Sixty-five study cohorts (40,062 participants) assessed the accuracy of Type 1 tests using microscopy as the reference standard; 16 study cohorts (13,010 participants) did the same for a Type 4 test, eight for a Type 2 test (3397 participants), five for a Type 3 test (958 participants) and three for a Type 5 test (1777 participants). Seventy-five cohorts (43,307 participants) assessed the accuracy of HRP-2 antibody-based tests and 19 cohorts (14,787) assessed the accuracy of pLHD antibody-based tests. Only four studies used PCR and one used PCR-adjusted microscopy. A summary of the numbers of studies assessing each RDT type using microscopy, PCR or PCR-adjusted microscopy is shown in Table 3.

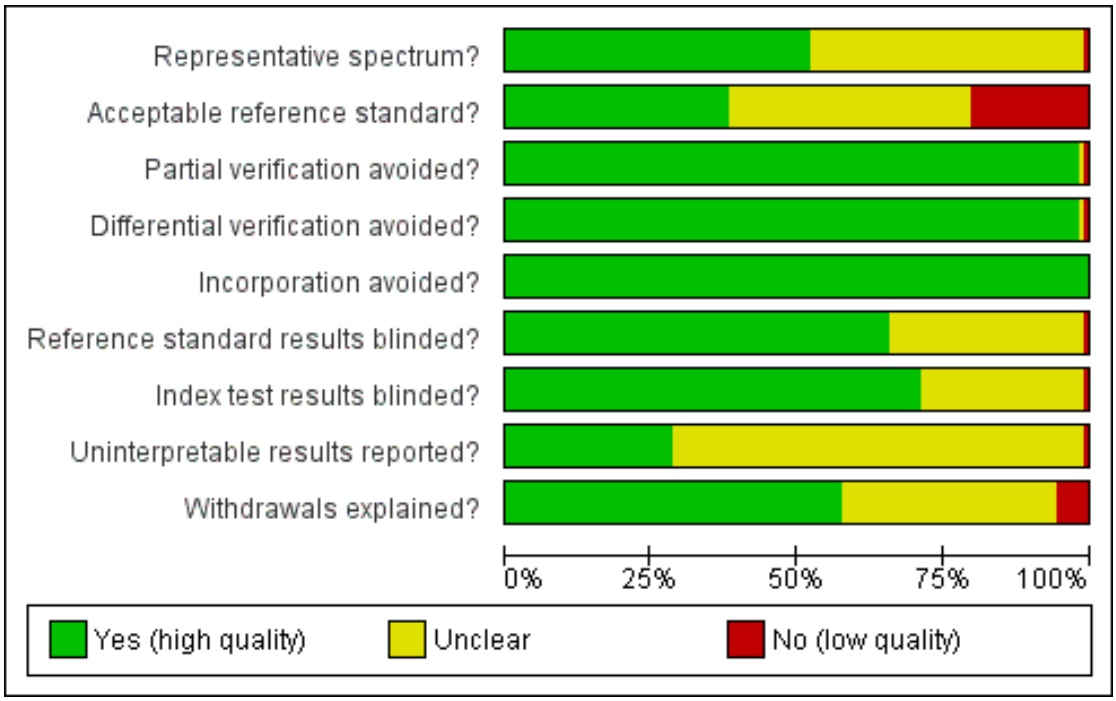
Table 3. Number of studies verifying each RDT type with reference standard

Type of RDT	Number of study cohorts (test evaluations if different) by reference standard		
	Microscopy	PCR	PCR-adjusted microscopy
Type 1	65 (71)	2	1
Type 4	16 (17)	1	0
Type 2	8	0	0
Type 3	5	1	1
Type 5	3	0	0
Type 6	0	1	0

Methodological quality of included studies

The overall methodological quality of all included study cohorts is summarized in Figure 2. Just over 50% clearly included a representative spectrum of participants attending ambulatory care settings with symptoms suggestive of malaria; the majority of the remaining studies were unclear, in most cases because they had not described the sampling methods. Around 40% reported an acceptable reference standard, 40% were unclear about the microscopy method, and 20% reported an unacceptable quality reference standard (heterogeneity relating to this criteria is investigated below). As expected, almost all the included studies reported avoidance of partial verification and differential verification, and all reported avoidance of incorporation bias. Around 65% of study cohorts reported blinding of the reference standard to the results of the index test, and around 70% reported blinding of the index test to the results of the reference standard. Only around 25% of studies reported on uninterpretable results while around 60% either explained any withdrawals or were clear that there were no withdrawals.

Figure 2. Methodological quality graph: review authors' judgements about each methodological quality item presented as percentages across all included studies.



Twenty-four of the included studies gave details of the number of uninterpretable or invalid RDT results. Eight reported no uninterpretable RDT results; one reported that 14% of tests needed to be repeated; and 15 reported small numbers of uninterpretable test results (<1% to 5%), which were excluded from the analysis. Four studies reported small numbers of uninterpretable microscopy slides, which were excluded from the analysis.

Four key quality items (representative spectrum, adequate reference standard, blinding of reference test, and index test) are used to evaluate each RDT type in Table 4. A lower proportion of those studies assessing Type 1 and Type 4 RDTs reported an adequate reference standard than those assessing other RDT types (P=0.05) (only 25% of Type 1 evaluations and 29% of Type 2 evaluations were judged to be adequate).

Table 4. Methodological quality by RDT type

Test type	Test evaluations	Representative spectrum	Adequate reference standard	Blinded reference standard	Blinded index test
Type 1	71	38 (54%)	18 (25%)	44 (62%)	50 (70%)
Type 2	8	2 (25%)	4 (50%)	6 (75%)	7 (88%)
Type 3	5	4 (80%)	2 (40%)	4 (80%)	4 (80%)
Type 4	17	9 (53%)	5 (29%)	10 (59%)	12 (71%)
Type 5	3	1 (33%)	3 (100%)	2 (67%)	3 (100%)
Test for difference between types		P = 0.54	P = 0.05	P = 0.93	P = 0.84

Findings

PRIMARY COMPARISONS - MICROSCOPY AS THE REFERENCE STANDARD

HRP-2 antibody-based tests

Type 1 tests

There were 71 evaluations of Type 1 RDTs verified with microscopy (based on data from 40,062 individuals in 65 cohorts described in 55 publications); forty-one were conducted in Africa, 28 in Asia and two in South America. The median sample size was 269 (range 30 to 7000), and the median prevalence of *falciparum* malaria parasitaemia was 30% (range 1% to 92%). Only nine of the 71 evaluations were undertaken exclusively in children under the age of five. Ten different RDT brands were evaluated: Paracheck-Pf (27), ParaSight (17), ICT Malaria Pf (16), ParaHIT-F (4), PATH (2), Determine Malaria Pf (1), Rapid Test Malaria (1), Diaspot Malaria (1), New mini-Pf (1), and Hexagon Malaria (1). The earliest study was published in 1996, with the majority published between 1999 and 2007.

Sensitivities of the tests ranged from 42% to 100%, specificities from 65% to 100% (Figure 3). The meta-analytical average sensitivity and specificity (95% confidence interval (CI)) were 94.8% (93.1% to 96.1%) and 95.2% (93.2% to 96.7%), respectively, but heterogeneity was noted between studies. Comparing the ten RDT brands in an analysis of the 71 evaluations revealed

no statistically significant differences (P = 0.18), although differences may be masked by the high between study heterogeneity (Table 5, see Appendix 4 for extra figures). In an analysis restricted only to the four brands evaluated in more than 1000 patients (Paracheck-Pf, ParaSight, ICT Malaria Pf, ParaHIT-F), pairwise comparisons indicated that ICT Malaria Pf was significantly more sensitive than Paracheck-Pf and ParaSight-F (97.7% compared to 93.3% and 94.2%, respectively), whilst ParaHIT-F was significantly more specific than Paracheck-Pf, ParaSight-F, and ICT Malaria Pf (98.9% compared to 95.7%, 94.5% and 94.5%, respectively) (see Appendix 5). However, these differences were small and are based on between-study comparisons, so may have been due to differences between the studies rather than true differences between the test brands.

Figure 3. Study results of Type 1 RDTs plotted in ROC space (by RDT brand)

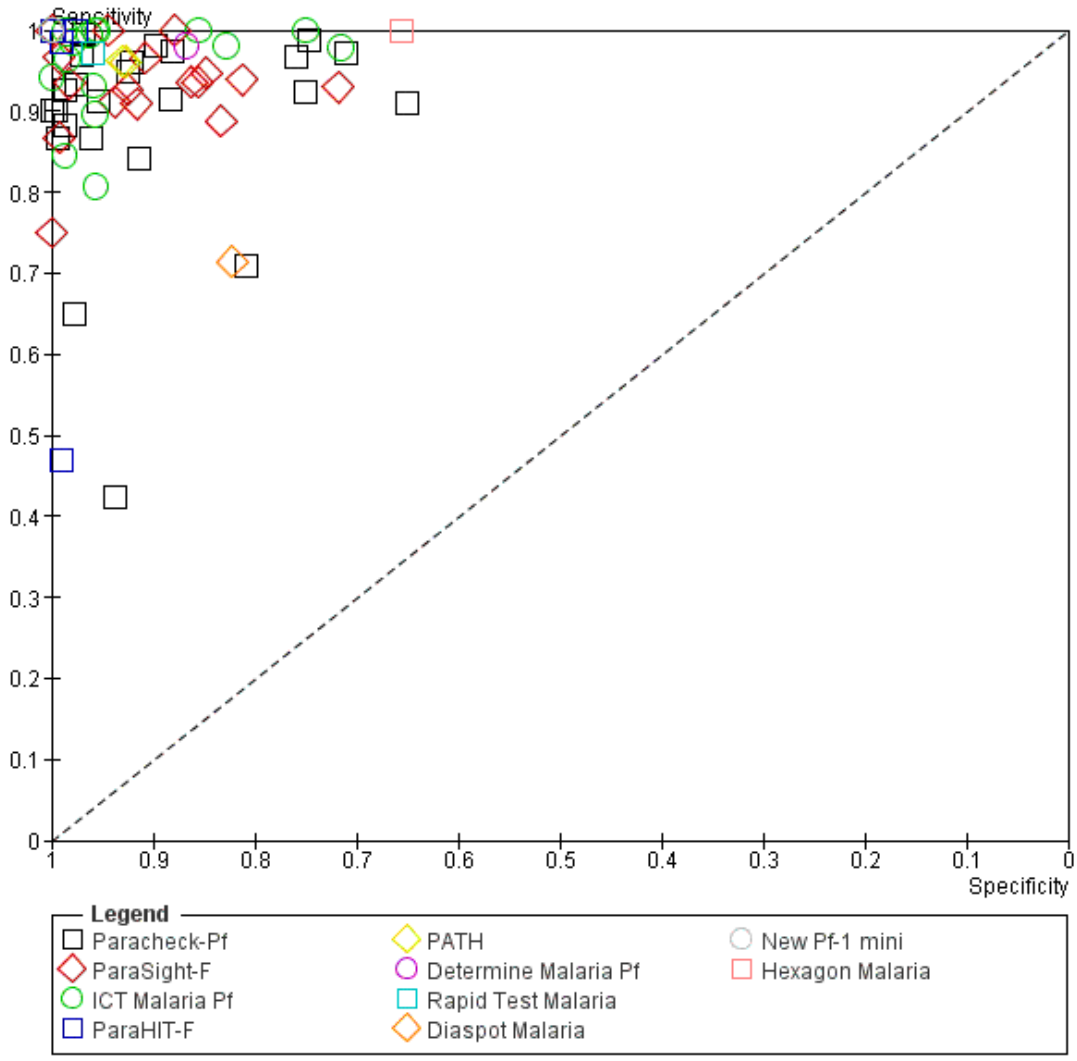


Table 5. RDT types and brands verified with microscopy

RDT Brand	Study cohorts (n)	Patients (n)	*P. falciparum* cases (n)	Pooled sensitivity (95% CI)	Pooled specificity (95% CI)	Test[1]
Type 1 Brands						
Paracheck-Pf	27	22,319	6929	93.2 (89.7, 95.6)	95.6 (92.8, 97.3)	P = 0.15
ParaSight-F	17	12,521	3261	94.1 (89.9, 96.6)	94.6 (90.4, 96.8)	

Table 5. RDT types and brands verified with microscopy (*Continued*)

ICT Malaria-Pf	16	2955	1200	97.6 (95.5, 98.8)	94.5 (90.5, 96.9)	
ParaHIT-F	4	1119	192	92.3 (74.9, 98.0)	98.9 (94.9, 99.8)	
Determine Malaria-Pf	1	526	262	98.2 (85.4, 99.8)	86.8 (35.1, 98.8)	
PATH	2	378	180	96.6 (83.8, 99.3)	93.3 (68.6, 98.9)	
Rapid Test Malaria	1	306	36	97.8 (70.1, 100.0)	96.1 (65.6, 99.7)	
DiaSpot Malaria	1	153	63	71.8 (23.1, 95.6)	82.6 (27.3, 98.4)	
Hexagon Malaria	1	119	32	100.0 (.)	65.7 (13.4, 96.0)	
New Pf-1 mini	1	10	6	100.0 (0, 100.0)	100.0 (.)	
Combined[2]	65	40,062	11,966	94.8 (93.1, 96.1)	95.2 (93.2, 96.7)	
Type 2 Brands						
ICT Malaria Pf/Pv	6	2255	600	96.0 (93.6, 97.5)	95.6 (86.1, 98.7)	P = 1.0
Now Malaria ICT	2	1142	190	96.0 (91.6, 98.1)	94.1 (66.6, 99.2)	
Combined	8	3397	790	96.0 (94.0, 97.3)	95.3 (87.3, 98.3)	
Type 3 (too few studies to stratify by brand)						
Combined	5	958	330	99.5 (71.0, 100.0)	90.6 (80.5, 95.7)	
Type 4 Brands						
OptiMAL	10	3393	833	90.1 (86.3, 92.9)	99.3 (98.0, 99.8)	P = 0.009
Carestart Pf/Pan	2	537	240	97.8 (94.1, 99.2)	92.2 (72.4, 98.1)	
OptiMAL-IT	3	1356	280	87.4 (79.9, 92.4)	97.0 (88.4, 99.3)	
Parabank	2	7918	2992	87.9 (82.0, 92.0)	98.8 (90.9, 99.9)	
Combined[3]	16	13,010	4274	91.5 (84.7, 95.3)	98.7 (96.9, 99.5)	

Table 5. RDT types and brands verified with microscopy (*Continued*)

Type 5 Brands (too few studies to stratify by brand)						
Combined[4]	3	1777	400	98.4 (95.1, 99.5)	97.5 (93.5, 99.1)	

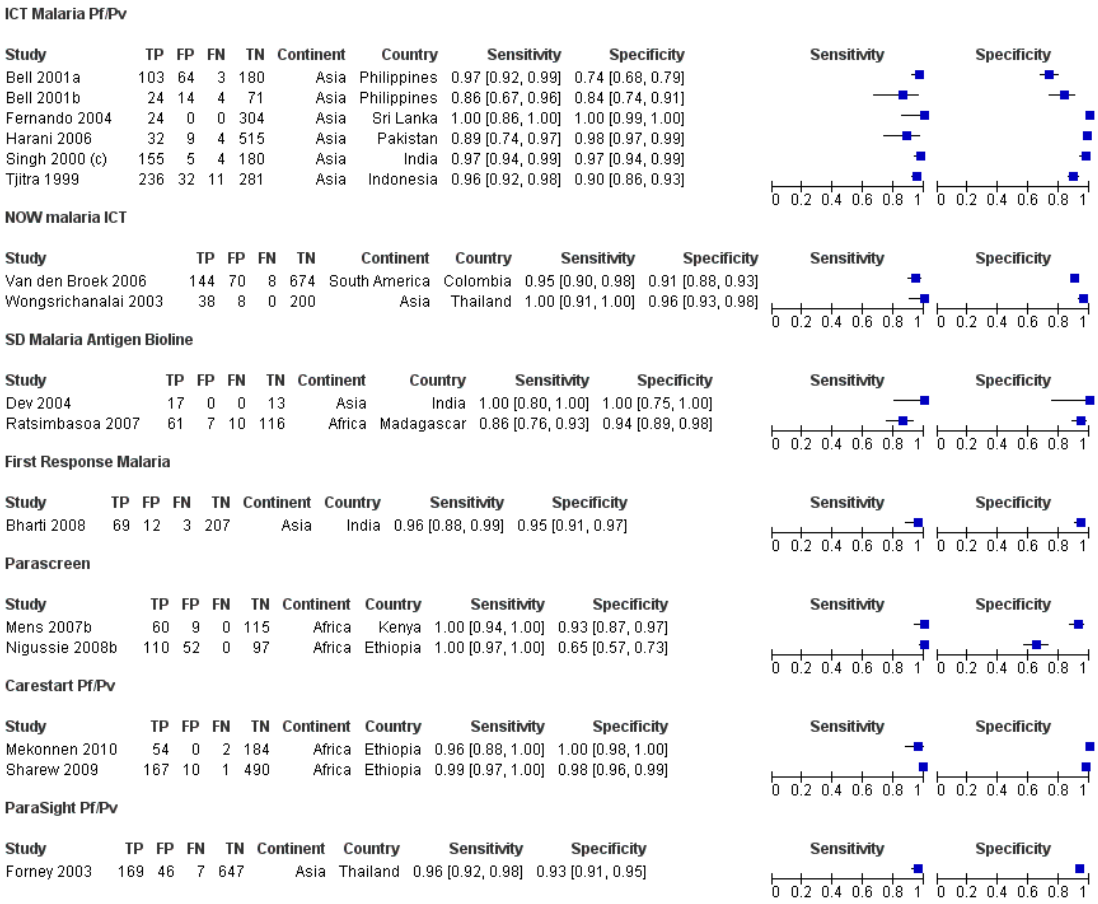
1 Likelihood ratio test for evidence of a difference between brands.
2 65 study cohorts evaluated 71 different tests. Only one test (selected randomly) from each cohort is included in the combined analysis.
3 16 study cohorts evaluated 17 different tests. Only one test (selected randomly) from each cohort is included in the overall analysis.
4 HSROC model fitted assuming no correlation between sensitivity and specificity.

Type 2 tests

There were eight evaluations of Type 2 RDTs verified with microscopy (based on data from 3397 individuals in eight cohorts described in seven publications); seven were conducted in Asia and one in South America. The median sample size was 347 (range 113 to 896), and the median prevalence of *falciparum* malaria parasitaemia was 21% (range 6% to 46%). None of the evaluations were undertaken exclusively in children under the age of five. Two different RDT brands were evaluated: ICT Malaria Pf/Pv (6) and NOW ICT Malaria (2). The earliest study was published in 1999, with the majority published between 2000 and 2005.

Sensitivities of the tests ranged from 86% to 100%, specificities from 74% to 100% (Figure 4). The meta-analytical average sensitivity and specificity (95% CI) were 96.0% (94.0% to 97.3%) and 95.3% (87.3% to 98.3%), respectively. Comparing the two RDT brands in an analysis of the eight evaluations showed no statistically significant differences (P = 1.0) (Table 5, see Appendix 4 for extra figures).

Figure 4. Forest plot of study results of Type 2, 3 and 5 RDTs (by RDT brand)



Type 3 tests

There were five evaluations of Type 3 RDTs verified with microscopy (based on data from 958 individuals in five cohorts described in five publications); three were conducted in Africa and two in Asia. The median sample size was 194 (range 30 to 291), and the median prevalence of *falciparum* malaria parasitaemia was 37% (range 25% to 57%). One of the evaluations was undertaken exclusively in children under the age of five. Three different RDT brands were evaluated: SD Malaria Antigen Bioline (2), Parascreen (2), and First Response Malaria (1). The earliest study was published in 2004.

Sensitivities of the tests ranged from 86% to 100%, specificities from 65% to 100% (Figure 4). The meta-analytical average sensitivity and specificity (95% CI) were 99.5% (71.0% to 100%) and 90.6% (80.5% to 95.7%), respectively. There were inadequate data on each RDT brand to make formal statistical comparisons (see Appendix 4 for extra figures).

Type 6 tests

No studies assessed the accuracy of Type 6 RDTs verified with microscopy.

All HRP-2 antibody based tests

There were 84 evaluations of HRP-2 tests verified with microscopy (based on data from 43,307 individuals in 75 cohorts described in 64 publications); forty-two cohorts were conducted in Africa, 31 in Asia and two in South America. The median sample size was 291 (range 30 to 7000), and the median prevalence of *falciparum* malaria parasitaemia was 26% (range 1% to 84%). Nine of the

evaluations were undertaken exclusively in children under the age of five. Sensitivities of the tests ranged from 42% to 100%, and specificities ranged from 65% to 100%. The meta-analytical average sensitivity and specificity (95% CI) were 95.0% (93.5% to 96.2%) and 95.2% (93.4% to 99.4%), respectively.

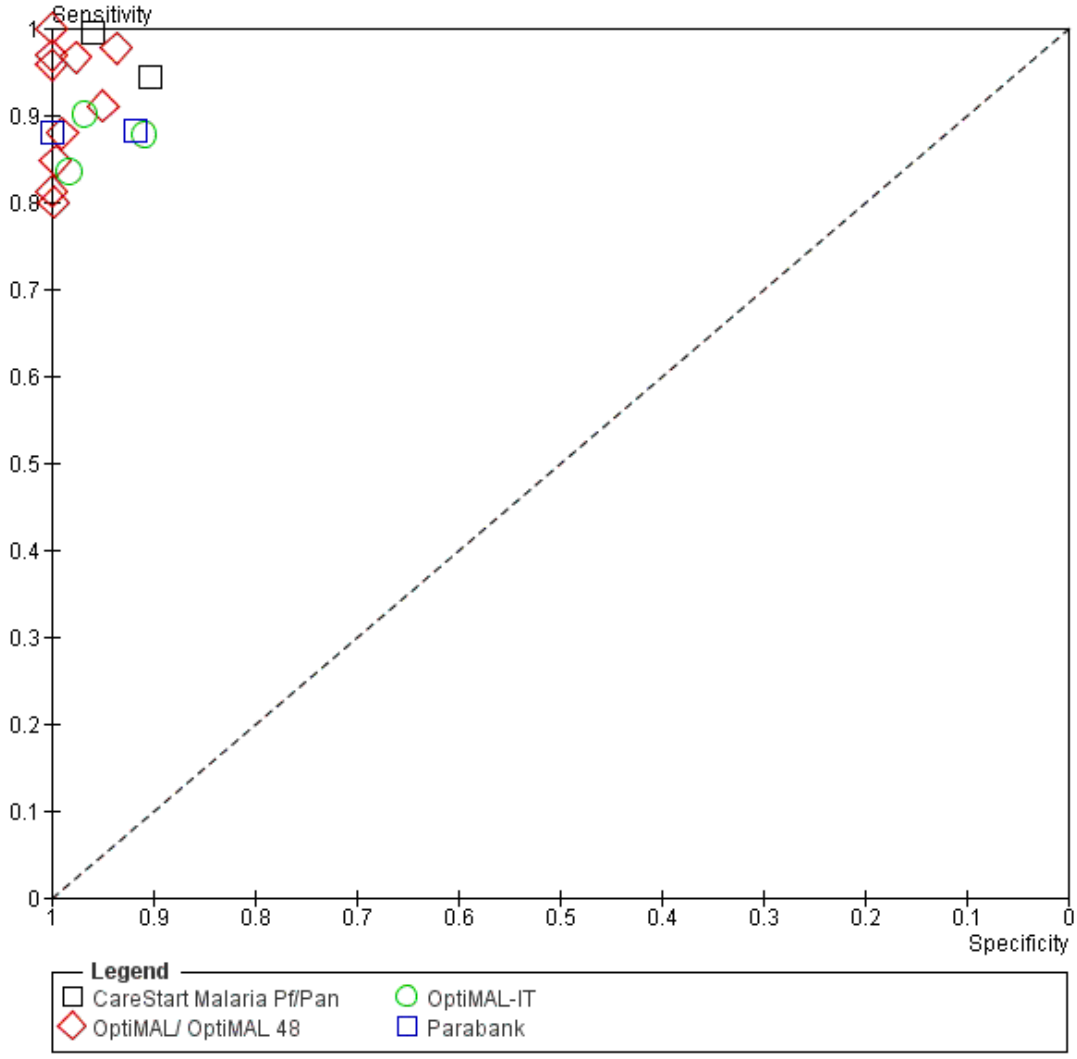
pLDH antibody based tests

Type 4 tests

There were 17 evaluations of Type 4 RDTs verified with microscopy (based on data from 13,010 individuals in 16 cohorts described in 14 publications); eight were conducted in Africa, eight in Asia and one in South America. The median sample size was 305 (range 75 to 7000), and the median prevalence of *falciparum* malaria parasitaemia was 32% (range 2% to 61%). Only four of the 17 evaluations were undertaken exclusively in children under the age of five. Four different brands were assessed: OptiMAL (10), OptiMAL-IT (3), Parabank (2) and Carestart Malaria Pf/Pan (2). The earliest study was published in 1999, with the majority published between 2003 and 2007.

Sensitivities of the tests ranged from 80% to 100%, specificities from 90% to 100% (Figure 5). The meta-analytical average sensitivity and specificity (95% CI) were 91.5% (84.7% to 95.3%) and 98.7% (96.9% to 99.5%), respectively. Comparing the four RDT brands in an analysis of the 17 evaluations revealed statistically significant differences (P = 0.009) (Table 5). Carestart Malaria Pf/Pan was observed to have a higher sensitivity and lower specificity than either OptiMAL, OptiMAL-IT or Parabank (sensitivity of 97.8% compared with 90.1%, 87.4% and 87.9%, respectively; specificity of 92.2% compared with 99.3%, 97.0% and 98.8%, respectively). See Appendix 4 for extra figures. These differences are based on between-study comparisons, so may have been due to differences between the studies rather than true differences between test brands.

Figure 5. Study results of Type 4 RDTs plotted in ROC space (by RDT brand)



Type 5 tests

There were three evaluations of Type 5 RDTs verified with microscopy (based on data from 1777 individuals in three cohorts described in three publications); two were conducted in Africa, one in Asia and none in South America. The median sample size was 668 (range 240 to 869), and the median prevalence of *falciparum* malaria parasitaemia was 23% (range 20% to 25%). None of the evaluations were undertaken exclusively in children under the age of five. Two different RDT brands were evaluated: Carestart Pf/Pv (2), and ParaSight Pf/Pv (1). The earliest study was published in 2003.

Sensitivities of the tests ranged from 96% to 99%, specificities from 93% to 100% (Figure 4). The meta-analytical average sensitivity and specificity (95% CI) were 98.4% (95.1% to 99.5%) and 97.5% (93.5% to 99.1%), respectively. There were inadequate data on each RDT brand to make formal statistical comparisons. See Appendix 4 for extra figures.

All pLDH antibody based tests

There were 20 evaluations of pLDH antibody-based tests verified with microscopy (based on data from 14,787 individuals in 19 cohorts described in 17 publications); nine cohorts were conducted in Africa, nine in Asia and one in South America. The median sample size was 343 (range 75 to 7000) and the median prevalence of *falciparum* malaria parasitaemia was 28% (range 2% to 58%). Four of the evaluations were undertaken exclusively in children under the age of five.

Sensitivities of the tests ranged from 80% to 100% and specificities ranged from 90% to 100%. The meta-analytical average sensitivity and specificity (95% CI) were 93.2% (88.0% to 96.2%) and 98.5% (96.7% to 99.4%), respectively.

Comparisons between RDT types

Statistical comparisons could only be made between Type 1 and Type 4 tests, as the number of studies evaluating other test types was inadequate to provide stable estimates of comparisons in the meta-analytical models. Models were fitted allowing for different degrees of heterogeneity for the two test types: results for Type 1 were more heterogeneous than Type 4. Significant differences in test accuracy (P = 0.009) were noted between Type 1 and Type 4 RDTs: Type 4 tests tended to have slightly lower sensitivity (P = 0.34) but significantly higher specificity (P < 0.001) than Type 1 tests in the comparisons based on all data (shown graphically in Figure 6). When the analysis was restricted to the seven studies with direct comparisons, the same patterns were evident, but none were statistically significant (Table 6). Based on estimates from all studies, Type 1 tests detect on average three more cases out of every 100 people with malaria than Type 4 tests (P = 0.20), but give on average three more false positive diagnoses for every 100 people without malaria (P < 0.001).

Figure 6. Summary ROC Plot comparing different RDT types verified with microscopy (points are meta-analytical estimates, regions are 95% confidence regions, no regions could be computed for Type 2 and 5 due to small numbers of studies)

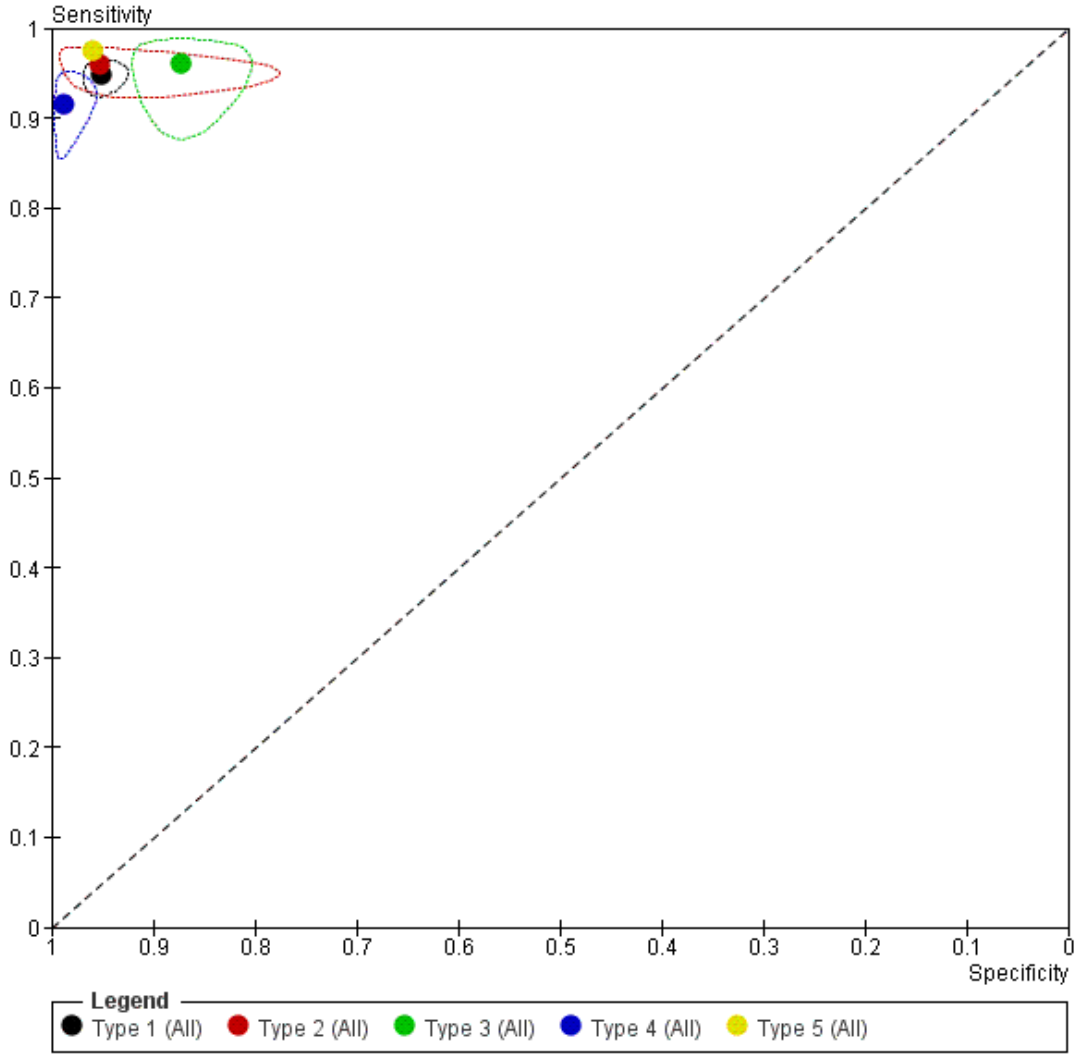


Table 6. Comparison of antibody and RDT types verified with microscopy

	Number of studies	Number of patients	Number of *P. falciparum cases*	Pooled sensitivity (95% CI)	Pooled specificity (95% CI)	Test[1]
Antibody-based test: indirect comparison (using all studies)						
HRP-2 based	75	43,307	12,857	95.0 (93.5, 96.2)	95.2 (93.4, 96.6)	
pLDH based	19	14,787	4674	93.2 (88.0, 96.2)	98.5 (96.7, 99.4)	
Ratio				*0.98 (0.94, 1.02), P = 0.34*	*1.03 (1.02, 1.05), P < 0.001*	*P = 0.01*
Antibody-based test: direct comparison (using only studies that directly compared the two)						
HRP-2 based	9	10,626	3672	95.6 (90.0, 98.1)	95.8 (84.7, 98.9)	
pLDH based	9	10,623	3672	94.8 (84.1, 98.2)	98.1 (87.8, 99.7)	
Ratio				*0.99 (0.94, 1.04) P = 0.60*	*1.02 (0.98, 1.07), P = 0.22*	*P = 0.35*
Test type: indirect comparison (using all studies of Type 1 and 4)						
Type 1	65	40,062	11,966	94.8 (93.0, 96.1)	95.2 (93.2, 96.7)	
Type 4	16	1,3010	4274	91.5 (84.7, 95.3)	98.7 (96.9, 99.5)	
Ratio				*0.96 (0.91, 1.02), P = 0.20*	*1.04 (1.02, 1.06), P < 0.001*	*P = 0.009*
Test type: direct comparison (using only comparative studies of Type 1 and 4)						
Type 1	7	9764	3433	94.5 (88.6, 97.4)	95.7 (72.2, 99.5)	
Type 4	7	9761	3433	92.0 (85.7, 94.8)	98.6 (80.0, 99.9)	
Ratio				*0.97 (0.87, 1.09), P = 0.51*	*1.03 (0.95, 1.11), P = 0.31*	*P = 0.26*

[1]Likelihood ratio test for evidence of a difference between test accuracy estimates between antigen and RDT types.

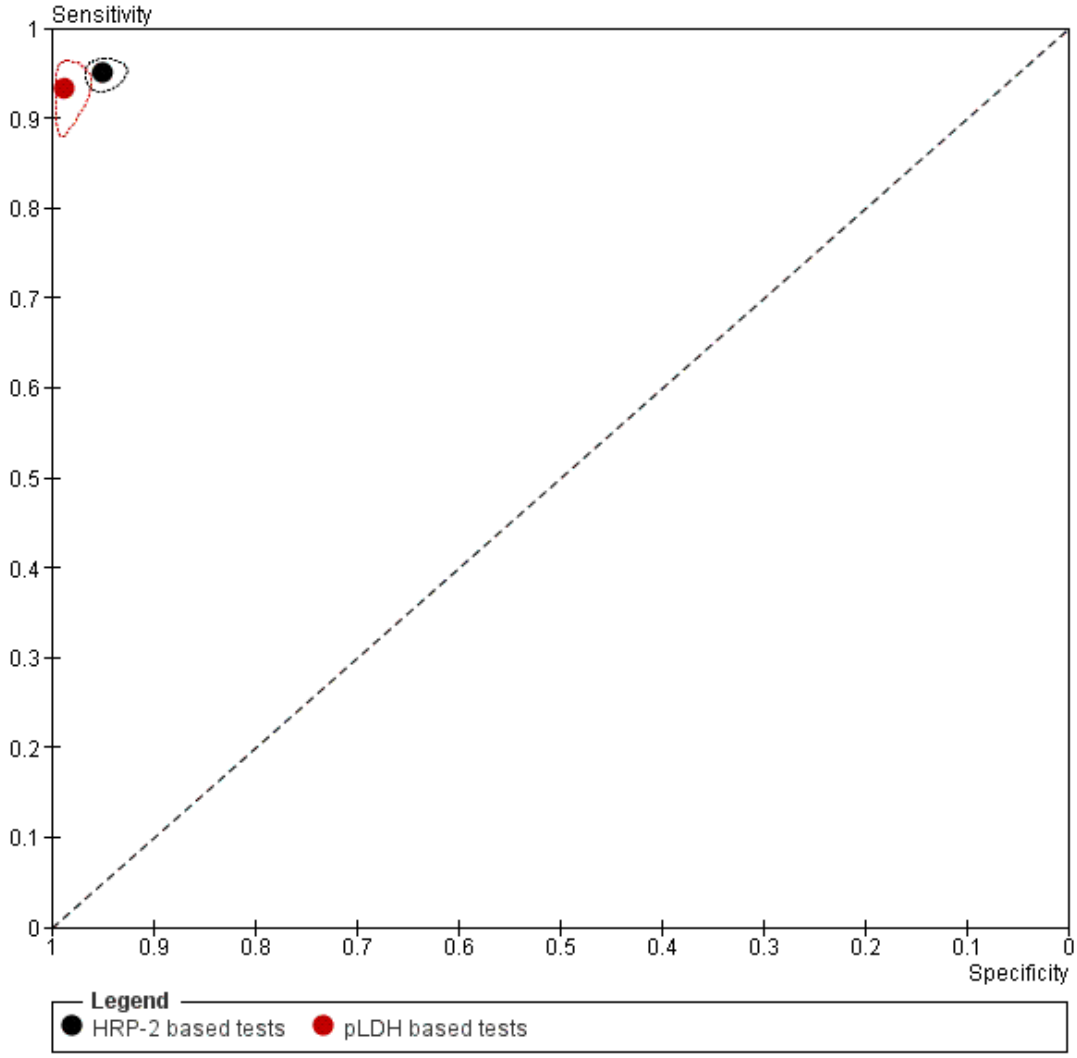
Four further studies provided direct comparisons between tests (Appendix 6). One study showed Type 2 to have higher sensitivity than Type 4, but lower specificity than both Type 4 and Type 1; another study showed that Type 3 tests had higher sensitivity than Type 1. The remaining studies showed no significant differences between types. As these comparisons are based on single small studies, their results should be interpreted with caution.

Comparisons between HRP-2 and pLDH antibody based RDT Types

RDT types 1 to 3 are all based on HRP-2 antibodies, while types 4 and 5 are related to detection of pLDH antigen. The process of grouping types based on this antibody classification is dominated by the results of the Type 1 tests (which constitute 65 out of 75 of the included HRP-2 antibody-based test studies) and Type 4 tests (which constitute 16 out of 19 of the included pLDH antibody-based test studies). Nine studies provide direct within-participant comparisons of HRP-2 and pLDH test types, eight of which are comparisons of a Type 1 test with a Type 4 test. As for Type 1 and Type 4 tests, it was necessary to allow for different heterogeneity between the test types in the meta-analytical model.

On average, HRP-2 antibody-based tests tend to have slightly higher sensitivity (P = 0.34) but significantly lower specificity (P<0.001) than pLDH antibody-based tests, based on analysis of all data (Table 6; Figure 7). Differences based on direct comparisons showed the same pattern, but none of the differences were statistically significant. For every 100 malaria cases, around two more are detected with HRP-2 antibody-based tests than pLDH antibody-based tests (P = 0.34 in analysis based on all data, P=0.60 in analysis based on within-study comparisons), but this is at the cost of four false positives for every 100 people without malaria (P < 0.001 in analysis based on all data, P = 0.22 in analysis based on within-study comparisons).

Figure 7. Summary ROC Plot comparing HRP-2-based and pLDH-based RDTs across all studies verified with microscopy (points are meta-analytical estimates, regions are 95% confidence regions)



Investigations of heterogeneity

Heterogeneity investigations were undertaken to test for differences in RDT performance related to age, endemicity, geographical location and the use of an adequate reference standard. Analyses were restricted to the 65 test cohorts in which RDTs of Type 1 were evaluated. Results are presented in Table 7.

Table 7. Investigations of heterogeneity between studies of Type 1 RDTs

	Number of studies	Number of patients	Number of *P. falciparum* cases	Pooled sensitivity (95% CI)	Pooled specificity (95% CI)	Test[1]
Age						
Mixed ages	29	23,967	7536	93.8 (90.6, 96.0)	94.2 (90.7, 96.5)	P = 0.41
Children only	9	2261	907	94.1 (87.2, 97.4)	93.4 (84.6, 97.3)	
Not stated	27	13,834	3523	95.9 (93.4, 97.5)	96.2 (93.7, 97.8)	
Endemicity						
Low	51	29,305	7671	95.1 (93.1, 96.6)	95.9 (94.1, 97.2)	P = 0.22
High	10	1824	806	93.7 (87.0, 97.1)	89.6 (78.3, 95.3)	
Mixed	4	8933	3489	93.2 (81.1, 97.8)	92.5 (76.5, 97.9)	
Adequate reference standard						
No	15	5499	1869	93.7 (88.6, 96.6)	95.5 (91.1, 97.7)	P = 0.34
Unclear	32	13,481	3439	95.4 (92.8, 97.1)	96.2 (93.9, 97.7)	
Yes	18	21,082	6658	94.6 (90.9, 96.9)	92.1 (86.0, 95.7)	
Continent						
Africa	39	21,958	7445	94.0 (91.3, 95.9)	93.0 (89.8, 95.3)	P = 0.01
Asia	24	1,5810	4060	96.7 (93.7, 97.8)	96.7 (94.4, 98.1)	
South America	2	2294	461	88.7 (61.9, 97.4)	99.4 (96.4, 100.0)	
Continent (South America excluded)						
Africa	39	21,958	7445	94.0 (91.2, 96.0)	93.1 (89.7, 95.3)	P = 0.03
Asia	24	15,810	4060	96.4 (93.7, 97.9)	96.6 (94.0, 98.1)	

[1]Likelihood ratio test for model with and without the covariate.

Nine study cohorts only recruited children aged five years or under, 28 recruited mixed age groups, and in 27 age distributions were not described. No difference in test accuracy was noted by age category (P = 0.41).

Fifty-one study cohorts were in low endemicity areas, 10 in high areas, and three were categorized as being in areas of mixed endemicity. Although specificity appeared to be lower in high endemicity areas, the differences were not statistically significant (P = 0.22).

Significant differences were seen by continent, with lower sensitivity (by 2.7%) and specificity (by 3.7%) in Africa than Asia (P = 0.01). Results from the South American studies showed very high specificity (99.4%) and low sensitivity (88.7%), but should be judged with caution due to only two studies being available.

Fifteen of the Type 1 study cohorts used inadequate reference standards and in 32 the reference standard was unclear, but their results did not differ significantly from the 17 with adequate reference standards (P = 0.34).

Sensitivity analysis

For all the above analyses, a sensitivity analysis was undertaken by including the one study in the review (Hopkins 2008b) that used PCR-adjusted microscopy as the reference standard; its inclusion made no difference to any of the findings.

OTHER ANALYSES

Use of PCR as a reference standard

Five study cohorts (from four studies) used PCR as a reference standard: two Type 1 RDTs (ParaSight-F and ParaHIT-F), one Type 3 RDT (SD Malaria Antigen Bioline), one Type 4 RDT (OptiMAL-IT) and one Type 6 RDT (PALUTOP). Comparisons were made with the corresponding microscopy evaluations for the first four of these tests (Appendix 7). Use of PCR as a reference standard reduced estimates of the sensitivity of the RDTs but increased estimates of specificity compared with the microscopy-based reference standard for three of the four studies in which comparison was possible.

For two studies, results are available separately using microscopy and PCR reference standards (Banchongaksorn 1996b; Nicastri 2009b). In one study (Banchongaksorn 1996a; Banchongaksorn 1996b), both sensitivity and specificity for PCR and microscopy were within 1% of each other. In the other (Nicastri 2009a; Nicastri 2009b), specificities were 99% when verified by microscopy and 100% when verified by PCR; sensitivity verified with microscopy was 47% (95% CI 29% to 65%) compared with 72% (95% CI, 51% to 88%) for PCR. In this study with 336 participants, 26 were positive for malaria by PCR, 32 by microscopy and 18 by RDT, suggesting a relatively high rate of false positives for microscopy in the context of a low prevalence.

Five of the included studies presented data, in addition to the comparisons included in the review, on the accuracy of their microscopy reference standard against PCR (excluding one study with only two microscopy positive cases). In three studies, where the quality of the microscopy was unclear (Gaye 1999; Mens 2007b; Nicastri 2009b), sensitivity of microscopy against PCR varied between 69% and 89%; in two studies with adequate quality microscopy (Banchongaksorn 1996b; Rakotonirina 2008), sensitivity varied between 90% and 96%. Specificity of microscopy against PCR was high in all five studies, varying between 96% and 100%.

Comparing the accuracy of RDTs and local standard microscopy

In addition to the comparison of RDT against the 'gold standard' microscopy, seven of the included studies presented a comparison of local microscopy against reference standard microscopy. These studies reported widely differing results: one study showed local microscopy services to be slightly more accurate than RDTs (Kolaczinski 2004); three studies showing local microscopy to be extremely inaccurate, with very low specificities of 0% (A-Elgayoum 2009) to 25% (Tagbo 2007), or a sensitivity so low that only around half of cases were detected (De Oliveira 2009); and the others were intermediate but favouring RDTs. The findings of the two studies with an adequate reference standard are presented in Appendix 8.

Summary of results

Summary of results. New Summary of results table

What is the diagnostic accuracy of Rapid Diagnostic Tests for detecting malaria? What are the best types of tests?	
Patients/ populations	People presenting with symptoms suggestive of uncomplicated malaria
Prior testing	None

Summary of results. New Summary of results table (*Continued*)

Settings	Ambulatory healthcare settings in *P. falciparum* malaria endemic areas in Asia, Africa and South America
Index tests	Immunochromatography-based rapid diagnostic tests for *P. falciparum* malaria
Reference standard	Conventional microscopy or PCR
Importance	Accurate and fast diagnosis allows appropriate and quick treatment for malaria to be provided
Studies	Consecutive series of patients; 74 studies presented 111 test evaluations based on 60,396 patient test results
Quality concerns	Poor reporting of patient characteristics, sampling method and reference standard methods were common concerns

Test types	**Quantity of evidence**	**Brands (studies)**	**Average pooled results**	**Consequences in a cohort of 1000**		
				***P. falciparum* prevalence**	**Missed cases**	**Overtreated non-cases**
HRP-2 antibody-based tests compared with microscopy						
Type 1 HRP-2 (*P. falciparum* specific)	71 evaluations 40,062 participants 11,966 malaria cases	Paracheck-Pf (27), ParaSight (17), ICT Malaria Pf (16), ParaHIT-F (4), PATH (2), Determine Malaria Pf (1), Rapid Test Malaria (1), Diaspot Malaria (1), New mini-Pf (1), and Hexagon Malaria (1)	sens = 94.8% (93.1% to 96.1%)	30%	16	34
			spec = 95.2% (93.2% to 96.7%)	50%	26	24
Type 2 HRP-2 (*P. falciparum* specific) and aldolase (pan-specific)	8 evaluations 3397 participants 790 malaria cases	ICT Malaria Pf/Pv (6) and NOW ICT Malaria (2)	sens = 96.0% (94.0% to 97.3%)	30%	12	33
			spec = 95.3% (87.3% to 98.3%)	50%	20	24
Type 3 HRP-2 (*P. falciparum* specific)	5 evaluations 958 participants 330 malaria cases	SD Malaria Antigen Bioline (2)	sens = 99.5% (71.0%	30%	12	62

Summary of results. New Summary of results table (*Continued*)

and pLDH (pan-specific)		, Parascreen (2) , and First Response Malaria (1)	to 100.0%)			
			spec = 90.6% (80.5% to 95.7%)	50%	20	44
pLDH antibody-based tests compared with microscopy						
Type 4 pLDH (*P. falciparum* specific) and pLDH (pan-specific)	17 evaluations 13,010 participants 4274 malaria cases	OptiMAL (10), OptiMAL-IT(3), Parabank (2) and Carestart Malaria Pf/Pan (2)	sens = 91.5% (84.7% to 95.3%)	30%	26	9
			spec = 98.7% (96.9% to 99.5%)	50%	43	7
Type 5 pLDH (*P. falciparum* specific) and pLDH (*P. vivax*-specific)	3 evaluations 1777 participants 400 malaria cases	Carestart Pf/Pv (2), and ParaSight Pf/Pv (1)	sens = 98.4% (95.1% to 99.5%)	30%	5	18
			spec = 97.5% (93.5% to 99.1%)	50%	8	13
Comparisons						
Comparison	**Comparison type**	**Quantity of evidence and overall finding**	**Sensitivity**		**Specificity**	
Type 1 vs Type 4	All studies	65 Type 1 vs 16 Type 4 Overall significant difference in accuracy P = 0.009	Type 1 3.3% more sensitive than Type 4 (P = 0.20)		Type 4 3.5% more specific than Type 1 (P < 0.001)	
	Within studies	7 comparative studies No overall significant difference in accuracy P = 0.26	Type 1 2.5% more sensitive than Type 4 (P = 0.51)		Type 4 2.9% more specific than Type 1 (P = 0.31)	
HRP-2 vs pLDH	All studies	75 HRP-2 vs 19 pLDH	HRP-2 1.8% more sensitive than pLDH (P = 0.34)		pLDH 3.3% more specific than HRP-2 (P = 0.01)	

Summary of results. New Summary of results table (*Continued*)

		Overall significant difference in accuracy P = 0.01		
	Within studies	9 comparative studies No overall significant difference in accuracy P = 0.35	HRP-2 0.8% more sensitive than pLDH (P = 0.60)	pLDH 2.3% more specific than HRP-2 (P = 0.22)

DISCUSSION

Malaria diagnosis and treatment policies have shifted rapidly over the past few years. In 2006, in its guidelines on malaria treatment, the WHO abandoned presumptive treatment with ineffective or only partly effective treatments for the new ACTs. Now, in the second (2010) edition of these guidelines, parasitological diagnosis is expected (WHO 2010): "prompt parasitological confirmation by microscopy or alternatively by RDTs is recommended in all patients suspected of malaria before treatment is started". In primary care in most developing countries, prompt, accurate results from microscopy can't be delivered efficiently, and so demonstrating the sensitivity and specificity of these tests helps reassure policy makers pushing investment in and purchase of this technology.

For *P. falciparum* malaria, targeting treatment will help to reduce unnecessary drug use and thus help to avoid the development of drug resistance. The test will also help health workers exclude malaria as a cause of fever and thus improve the diagnosis and treatment of other infections. In addition, as malaria control improves as a result of all the new approaches including use of ACTs (Sinclair 2009) and other preventive measures such as impregnated mosquito nets (Lengeler 2004), transmission will drop, immunity will drop and thus prompt detection and treatment becomes even more important for reducing severe illness.

Thus, the current policy question is: how well do RDTs perform in diagnosing symptomatic patients compared to the previous standard of microscopy? There are subsidiary questions about how well the various types and individual commercial tests perform against microscopy and against each other. This information will help to inform choice, although factors such as price, product consistency, stability, and shelf life will also influence those decisions. In addition, areas vary in relation to malaria species not detected by these tests (*P. vivax* and other non-*falciparum* malaria species). Thus the choice of commercial product will also depend on whether it is important for clinicians to detect these species. For example, as malaria eradication proceeds and endemicity of malaria falls, being able to detect *P. vivax* is likely to become more important. In these circumstances, the sensitivity and specificity of the commercial product to *P. vivax* may be a factor in the choice of product. This is the subject of a forthcoming Cochrane review.

Summary of main results

The main results are summarized in the Summary of Results table (Summary of results).

- There is a large volume of research on the accuracy of RDTs in malaria endemic countries that required meta-analysis.

- In diagnosing *P. falciparum* malaria, all tests performed reasonably well. Most studies identified for the current review were carried out on Type 1 (HRP-2) and Type 4 (pLDH) test, with fewer reports available on the other HRP-2 tests (Types 2 and 3) and the other pLDH tests (Type 5).

- There is a trade-off between sensitivity and specificity for Type 1 and Type 4 tests. Type 1 tests were falsely negative in about 5% of *P. falciparum* cases and were falsely positive in about 5% of people without *P. falciparum*. Type 4 tests were falsely negative in 8% to 9% of cases but were falsely positive only in about 1% of non-malaria cases. The results are mirrored by the available direct within-study comparisons between tests (although results were not statistically significant). There were only two brands of Type 1 and Type 4 tests that failed to follow these patterns. These findings support the results of laboratory-based testing undertaken by WHO (WHO 2010a), and probably reflect the different antigens used by different test types. The lower specificity of Type 1 tests may be due to the use of HRP-2 antibodies, which can give a false positive result in cases where a person has recently been successfully treated for *P.*

falciparum malaria, due to persistent antigenaemia. Analysis of all HRP-2 antibody-based tests and all pLDH antibody-based tests was undertaken and gave similar results, but was dominated by Type 1 and Type 4 tests.

- The sensitivities and specificities of Type 2, Type 3 and Type 5 tests were similar to those of Type 1 and Type 4 tests, but these three types have not been evaluated widely and robust comparisons are not possible.

- Studies of Type 1 tests conducted in Africa reported slightly lower estimates of sensitivity and specificity than those conducted in Asia. The reasons for this are unclear, and may relate to the relative quality of the studies conducted in different locations, but are most likely due to higher rates of transmission and persistent antigenaemia in Africa.

- Reporting of studies is variable: 40% reported an adequate reference standard, 40% did not provide enough information to assess the quality of the reference standard and 20% reported an inadequate reference standard. Other published studies were excluded from the review due to inadequate reporting. It would be helpful in the future for diagnostic test accuracy studies to be more carefully reported on, using the STARD (Bossuyt 2003) criteria, to ensure their inclusion in meta-analyses.

Application of meta-analysis to hypothetical cohort

Table 1 (Summary of results) summarizes the findings of the review and applies them to two hypothetical cohorts of 1000 symptomatic patients. In one of the cohorts, the prevalence of *P. falciparum* malaria parasitaemia is 30%, while in the other cohort it is 50%.

***Falciparum* malaria prevalence at 30%:** on average, a Type 1 test would miss 16 *P. falciparum* cases, while a Type 4 test would miss 26 cases. In contrast, a Type 1 test would wrongly identify 34 non-cases as having *falciparum* malaria, whereas a Type 4 test would only wrongly identify nine non-cases as *falciparum* malaria.

***Falciparum* malaria prevalence at 50%:** on average, a Type 1 test would miss 26 cases of *falciparum* malaria, while a Type 4 test would miss 43 cases. In contrast, a Type 1 test would wrongly identify 24 non-cases as having *falciparum* malaria, whereas a Type 4 test would only wrongly identify seven non-cases as *falciparum* malaria.

At very low and very high *falciparum malaria prevalence:* the sensitivity advantage of Type 1 tests, in terms of cases not missed, is less. For example, where prevalence is 10%, Type 1 tests would result in five cases being missed and 43 non-cases incorrectly identified as *falciparum* malaria. At higher prevalence, the greater sensitivity of Type 1 tests makes a greater difference; at 80% prevalence, Type 1 tests would result in 42 missed cases compared with 68 missed cases with Type 4 tests.

The numbers of false positives presented should be viewed with caution, as some RDTs may be more sensitive than microscopy.

Strengths and weaknesses of the review

The results of this review are based on strict and careful searching, study inclusion, and data extraction. The strength of this review is that it allows an assessment to be made between types and brands of test, and also provides an accurate assessment of the trade-offs.

Completeness of evidence

This is a reasonably complete data set. We excluded 18 potentially eligible studies not published in English, 17 studies that did not provide enough information to accurately assess whether they met our inclusion criteria, and 12 studies that gave only calculated values where imputation was not possible. However, it is known that studies of diagnostic test accuracy tend to be poorly indexed (Whiting 2009), and we may therefore have missed some studies despite the comprehensive search; in fact, two of the included studies were identified only in an earlier, scoping search.

Accuracy of the reference standards used:

Microscopy is regarded as the gold standard for malaria, and hence is the primary comparison, although PCR may be more sensitive. Comparisons of microscopy and PCR showed that microscopy was highly accurate when the microscopy methods were classified as 'adequate', but less accurate when the microscopy methods were of poorer quality. However, the quality of the microscopy did not explain any heterogeneity in the meta-analysis of Type 1 tests and therefore is unlikely to be an important factor in the interpretation of the study findings.

Quality and quality of reporting of the included studies:

Many of the included studies was not well reported. For example, reference standards were often not well described, there was often insufficient methodological detail, and numbers sometimes did not add up.

Only 40% of the included studies reported an adequate reference standard and 20% reported an inadequate reference standard. In Type 1 test studies, which were generally older and of lower quality, only 25% reported an adequate reference standard. As the quality of the reference standard did not explain heterogeneity in this analysis, it seems unlikely that including studies with an unclear or inadequate reference standard caused any kind of bias. In addition, only half of the included studies were explicit about patient recruitment involving a consecutive or random series of patients. Blinding of the index and reference tests was reported in the majority of studies (65% and 70%, respectively). Only 60% of studies explained withdrawals or stated that there were none. Sampling did not seem to be a significant problem, as the tests were taken at the same time, and few lost or uninterpretable test results were reported.

Interpretability of subgroup analyses:

The subgroup analysis is interpreted in relation to the antigen type, test type, and brand, and appears to make sense, although a confounding effect of quality over time cannot be excluded with the newer tests. The differences in specificity observed between HRP-2 and pLDH antibody-based tests are significant and replicate those found in systematic laboratory-based in vitro studies

(WHO 2010a).

Completeness and relevance of the review:

This review covers *P. falciparum* malaria only, and stands alone as relevant to areas where *P. falciparum* malaria predominates. A further Cochrane diagnostic review in this series will cover *P. vivax* and other non-*falciparum* malaria species.

Applicability of findings to clinical practice and policy

We found no important differences in accuracy between different RDT brands within the same type. Where significant differences between tests were found, these differences were small, and were based on weaker between-study comparisons. For some types, there were insufficient data to analyse differences between brands. We found Type 1 RDTs to be more sensitive than Type 4, and HRP-2 antibody-based tests to be more sensitive than pLDH antibody-based tests, although the differences were not statistically significant. The direction of this finding corresponds closely with a similar analysis in a diagnostic test accuracy review of RDTs for travellers with fever returning from malaria endemic areas to non-endemic areas *(*Marx 2005). It also corresponds with laboratory-based testing undertaken by WHO (WHO 2010a), where Type 1 tests had a lower threshold for detection of parasitaemia than Type 4 tests. However, Type 4 tests and pLDH antibody-based tests tended to be more specific, and this difference was significant. This research assesses sensitivity and specificity in applied research settings. In the field, the quality of microscopy is likely to be lower and the RDTs may not be read so accurately (Hawkes 2009). Further research is required on effective implementation of RDTs, as they can only influence clinical practice if the results are believed and acted upon. There may be a reluctance on the part of both health providers and patients to believe negative RDT results, leading to unnecessary prescribing of antimalarials for negative cases (Tavrow 2000). Trials in this area are in the process of being summarized (Odaga 2011).

The consequences of a false positive are that someone may be treated for malaria when they are not infected. The consequences of a false negative in an endemic area, particularly when related to low parasitaemia, means the patient is unlikely to die. The infection may clear by itself, as people living in endemic areas have partial immunity; if it does not, the illness will recur and they would seek care again.

AUTHORS' CONCLUSIONS

Implications for practice

The high sensitivity and specificity of RDTs means they can replace or augment microscopy for diagnosing *P. falciparum* malaria.

The performance of RDT types varied but the differences were not large. HRP-2-based tests tended to be more sensitive and were significantly less specific than pLDH-based tests. Choice will depend on prevalence of malaria, and we provide data in this review to assist these decisions, although policy makers will also take into account other factors relating to cost and test stability.

Implications for research

Future studies should include comparisons between new RDTs and commonly-used Type 1 and/or Type 4 RDTs in the same patients.

Studies should be reported according to the STARD guidelines (Bossuyt 2003), which will also facilitate incorporation into meta-analysis.

Further research on effective implementation of RDTs within routine clinical practice is needed.

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* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

A-Elgayoum 2009

Clinical features and settings	**Presenting signs and symptoms:** Clinically suspected malaria **Previous treatment for malaria:** No exclusions based on previous treatment. Information on previous treatment collected, but actual data not provided. **Clinical setting:** Primary healthcare facilities **Country:** Khartoum state, central Sudan **Malaria endemicity:** Seasonal and low **Malaria endemic species:** *P. falciparum*
Participants	**Sample size:** 410 **Age:** All age groups eligible. Mean age 21 years. **Sex:** Both males and females eligible. Actual proportions of males and females in the participant population not stated. **Co-morbidities and pregnancy:** No exclusion criteria based on co-morbidities or pregnancy. No details of the frequency of these conditions in the participant population is presented. **Parasite density of microscopy positive cases:** Not presented
Study design	Enrolment was consecutive and prospective. One RDT was evaluated.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy thick and thin blood films **Person(s) performing microscopy:** Expert malaria microscopist **Microscopy setting:** Quality Assurance Laboratory **Number of high power fields examined before declaring negative:** 300 **Number of observer or repeats:** Not stated **Resolution of discrepancies between observers:** Not stated
Index and comparator tests	**Commerical name of RDT:** Paracheck Pf (Orchid Biomedical Systems, Goa, India) **Parasite(s) designed to detect:** *P. falciparum* **Designated Type:** Type 1 **Batch numbers:** Not stated **Transport and storage conditions:** Not stated **Person(s) performing RDT:** Technicians **RDT setting:** Primary healthcare facilities
Follow-up	Not applicable
Notes	**Source of funding:** PhD financial support from the Ministry of Higher Education and Scientific Research

Table of Methodological Quality

Item	Authors' judgement	Description

A-Elgayoum 2009 (*Continued*)

Representative spectrum? All tests	Yes	Participants were a consecutive sample of people presenting at healthcare facilities with clinically suspected malaria
Acceptable reference standard? All tests	Unclear	Unclear how many observer repeats were used, but the microscopy was described as the 'gold standard'
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Yes	Reported that the tests were performed blindly
Index test results blinded? All tests	Yes	Reported that the tests were performed blindly
Uninterpretable results reported? All tests	Unclear	Number enrolled in the study was explicitly stated and corresponded to the number presented in the analysis; therefore no withdrawals due to invalid results
Withdrawals explained? All tests	Yes	Number enrolled in the study was explicitly stated and corresponded to the number presented in the analysis; therefore no withdrawals

Abeku 2008a

Clinical features and settings	**Presenting signs and symptoms:** Clinically diagnosed malaria based on fever or history of fever and absence of any other obvious cause of fever **Previous treatment for malaria:** No exclusions based on previous malaria treatment. Information on previous treatment collected, but data not presented. **Clinical setting:** Government health centres **Country:** Uganda **Malaria endemicity:** Incidence 359.8 per 1,000 per year **Malaria endemic species:** *P. falciparum*
Participants	**Sample size:** 1237 **Age:** All age groups eligible. Actual age profile of participant population not presented, but it is clear that the sample contains both children and adults. **Sex:** Both males and females eligible. Actual proportions of males and females in the

	participant population not stated. **Co-morbidities and pregnancy:** No exclusion criteria based on co-morbidities or pregnancy. No details of the frequency of these conditions in the participant population is presented. **Parasite density of microscopy positive cases:** Not presented
Study design	Enrollment was consecutive and prospective. One RDT was evaluated.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy thick and thin blood films **Person(s) performing microscopy:** Experienced microscopists **Microscopy setting:** Not stated **Number of high power fields examined before declaring negative:** 200 **Number of observer or repeats:** Two independent microscopists **Resolution of discrepancies between observers:** By a third microscopist, who had the final say
Index and comparator tests	**Commerical name of RDT:** Paracheck Pf (Orchid Biomedical Systems, Goa, India) **Parasite(s) designed to detect:** *P. falciparum* **Designated Type:** Type 1 **Batch numbers:** Not stated **Transport and storage conditions:** Stored at room temperature within the temperature range recommended by the manufacturer and used within 24 months **Person(s) performing RDT:** Laboratory staff who had been trained in their use **RDT setting:** Health centres
Follow-up	Not applicable
Notes	**Source of funding:** Gates malaria Partnership and UK DFID

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	Yes	Participants were a consecutive series of people attending health centres with clinically suspected malaria
Acceptable reference standard? All tests	Yes	Two independent experienced microscopists examined at least 200 high power fields before declaring samples negative. Discordant results were resolved by a third microscopist in a double-blind manner.
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results

Abeku 2008a (*Continued*)

Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Yes	Study report states that microscopists were blinded to the RDT results
Index test results blinded? All tests	Yes	All RDTs were undertaken and the results known before microscopy
Uninterpretable results reported? All tests	Unclear	The number of participants originally enrolled in the study was not clear; therefore unclear whether there were any withdrawals due to invalid results
Withdrawals explained? All tests	Unclear	The number of participants originally enrolled in the study was not clear; therefore unclear whether there were any withdrawals

Abeku 2008b

Clinical features and settings	**Presenting signs and symptoms:** Clinically diagnosed malaria based on fever or history of fever and absence of any other obvious cause of fever **Previous treatment for malaria:** No exclusions based on previous treatment. Information on previous treatment collected, but data not presented. **Clinical setting:** Government health centres **Country:** Kenya **Malaria endemicity:** Incidence 43.2 per 1,000 per year **Malaria endemic species:** *P. falciparum*
Participants	**Sample size:** 1000 **Age:** All age groups eligible. Actual age profile of participant population not presented. **Sex:** Both males and females eligible. Actual proportions of males and females in the participant population not stated. **Co-morbidities and pregnancy:** No exclusion criteria based on co-morbidities or pregnancy. No details of the frequency of these conditions in the participant population is presented. **Parasite density of microscopy positive cases:** Not presented
Study design	Enrolment was consecutive and prospective. One RDT was evaluated.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy thick and thin blood films **Person(s) performing microscopy:** Experienced microscopists **Microscopy setting:** Not stated **Number of high power fields examined before declaring negative:** 200 **Number of observer or repeats:** Two independent microscopists **Resolution of discrepancies between observers:** By a third microscopist, who had the

Abeku 2008b (*Continued*)

	final say
Index and comparator tests	**Commerical name of RDT:** Paracheck Pf (Orchid Biomedical Systems, Goa, India) **Parasite(s) designed to detect:** *P. falciparum* **Designated Type:** Type 1 **Batch numbers:** Not stated **Transport and storage conditions:** Stored at room temperature within the temperature range recommended by the manufacturer and used within 24 months **Person(s) performing RDT:** Laboratory staff who had been trained in their use **RDT setting:** Health centres
Follow-up	Not applicable
Notes	**Source of funding:** Gates malaria Partnership and UK DFID

Table of Methodological Quality

Item	**Authors' judgement**	**Description**
Representative spectrum? All tests	Yes	Participants were a consecutive series of people attending health centres with clinically suspected malaria
Acceptable reference standard? All tests	Yes	Two independent experienced microscopists examined at least 200 high power fields before declaring samples negative. Discordant results were resolved by a third microscopist in a double-blind manner.
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Yes	Study report states that microscopist were blinded to the RDT results
Index test results blinded? All tests	Yes	All RDTs were undertaken and the results known before microscopy
Uninterpretable results reported? All tests	Unclear	The number of participants originally enrolled in the study was not explicitly stated; therefore unclear whether there were any withdrawals due to invalid results

Abeku 2008b (*Continued*)

Withdrawals explained? All tests	Unclear	The number of participants originally enrolled in the study was not explicitly stated; therefore unclear whether there were any withdrawals

Banchongaksorn 1996a

Clinical features and settings	**Presenting signs and symptoms:** All patients attending malaria clinics **Previous treatment for malaria:** No exclusions based on previous treatment. Information on previous treatment collected, but actual data not provided. **Clinical setting:** Two malaria clinics **Country:** Thailand (Tak Province and Trat province, East Thailand) **Malaria endemicity:** Not stated **Malaria endemic species:** *P. falciparum* and *P. vivax*
Participants	**Sample size:** 520 **Age:** All age groups eligible. Actual age profile of participant population not presented. **Sex:** Both males and females eligible. Actual proportions of males and females in the participant population not stated. **Co-morbidities and pregnancy:** No exclusion criteria based on co-morbidities or pregnancy. No details of the frequency of these conditions in the participant population is presented. **Parasite density of microscopy positive cases:** Not presented
Study design	Enrollment was consecutive and prospective. One RDT was evaluated.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy thick and thin blood films **Person(s) performing microscopy:** Microscopist and consultant **Microscopy setting:** Regional and national malaria centres **Number of high power fields examined before declaring negative:** 100 **Number of observer or repeats:** Two **Resolution of discrepancies between observers:** Not clear, 'the data were compared and confirmed'
Index and comparator tests	**Commerical name of RDT:** ParaSight-F (Beckton Dickinson, Franklin Lakes, NJ, US) **Parasite(s) designed to detect:** *P. falciparum* **Designated Type:** Type 1 **Batch numbers:** Not stated **Transport and storage conditions:** Not described **Person(s) performing RDT:** The study team **RDT setting:** Malaria clinics
Follow-up	Not applicable
Notes	**Source of funding:** WHO Regional Office for South East Asia, new Delhi, India. Also Dr Joe Perrone of Becton Dickinson provided the ParaSight-F kits

Banchongaksorn 1996a (*Continued*)

Table of Methodological Quality		
Item	**Authors' judgement**	**Description**
Representative spectrum? All tests	Yes	Participants were attending malaria clinics and therefore suspected themselves that they had malaria. It was a consecutive sample.
Acceptable reference standard? All tests	Yes	Two independent microscopists based at a central laboratory examined at least 100 high power fields before declaring a slide negative
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Yes	Report states that different tests were undertaken "independently"
Index test results blinded? All tests	Yes	Report states that different tests were undertaken "independently"
Uninterpretable results reported? All tests	Unclear	Number enrolled in the study was explicitly stated and corresponded to the number presented in the analysis; therefore no withdrawals due to invalid results
Withdrawals explained? All tests	Yes	Number enrolled in the study was explicitly stated and corresponded to the number presented in the analysis; therefore no withdrawals

Banchongaksorn 1996b

Clinical features and settings	**Presenting signs and symptoms:** All patients attending malaria clinics **Previous treatment for malaria:** No exclusions based on previous treatment. Information on previous treatment collected, but actual data not provided. **Clinical setting:** Two malaria clinics **Country:** Thailand (Tak Province and Trat province, East Thailand) **Malaria endemicity:** Not stated **Malaria endemic species:** *P. falciparum* and *P. vivax*
Participants	**Sample size:** 520 **Age:** All age groups eligible. Actual age profile of participant population not presented. **Sex:** Both males and females eligible. Actual proportions of males and females in the participant population not stated **Co-morbidities and pregnancy:** No exclusion criteria based on co-morbidities or pregnancy. No details of the frequency of these conditions in the participant population is presented. **Parasite density of microscopy positive cases:** Not presented
Study design	Enrollment was consecutive and prospective. One RDT was evaluated.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** PCR
Index and comparator tests	**Commerical name of RDT:** ParaSight-F (Beckton Dickinson, Franklin Lakes, NJ, US) **Parasite(s) designed to detect:** *P. falciparum* **Designated Type:** Type 1 **Batch numbers:** Not stated **Transport and storage conditions:** Not described **Person(s) performing RDT:** The study team **RDT setting:** Malaria clinics
Follow-up	Not applicable
Notes	**Source of funding:** WHO Regional Office for South East Asia, new Delhi, India. Also Dr Joe Perrone of Becton Dickinson provided the ParaSight-F kits

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	Yes	All participants were attending malaria clinics and therefore suspected themselves that they had malaria. Sampling was consecutive.
Acceptable reference standard? All tests	Yes	Reference standard was PCR
Partial verification avoided? All tests	No	913 participants received the index test, 520 received the reference tests

Banchongaksorn 1996b (*Continued*)

Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Yes	Report states that different tests were undertaken "independently"
Index test results blinded? All tests	Yes	Report states that different tests were undertaken "independently"
Uninterpretable results reported? All tests	Unclear	The number of participants originally enrolled in the study was not explicitly stated; therefore unclear whether there were any withdrawals due to invalid results
Withdrawals explained? All tests	Unclear	The number of participants originally enrolled in the study was not explicitly stated; therefore unclear whether there were any withdrawals

Banchongaksorn 1997

Clinical features and settings	**Presenting signs and symptoms:** Fever over 37.5 °C by oral thermometer **Previous treatment for malaria:** Not mentioned, but no indication of any exclusion criteria based on previous antimalarial use **Clinical setting:** 34 health centres and 22 mobile health units **Country:** Thailand (Chiang Mai and Mae Hong Son provinces) **Malaria endemicity:** Not stated **Malaria endemic species:** *P. falciparum* and *P. vivax*
Participants	**Sample size:** 3361 **Age:** All age groups eligible. Actual age profile of participant population not presented. **Sex:** Both males and females eligible. Actual proportions of males and females in the participant population not stated. **Co-morbidities and pregnancy:** No exclusion criteria based on co-morbidities or pregnancy. No details of the frequency of these conditions in the participant population is presented. **Parasite density of microscopy positive cases:** Not presented
Study design	Enrollment was prospective. The sampling method was not described. One RDT was evaluated.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy thick and thin blood films **Person(s) performing microscopy:** Expert microscopists **Microscopy setting:** Malaria Regional Centre, Chiang Mai

Banchongaksorn 1997 (*Continued*)

	Number of high power fields examined before declaring negative: Not stated **Number of observer or repeats:** Not stated **Resolution of discrepancies between observers:** Not applicable
Index and comparator tests	**Commerical name of RDT:** ParaSight-F (Beckton Dickinson, Franklin Lakes, NJ, US) **Parasite(s) designed to detect:** *P. falciparum* **Designated Type:** Type 1 **Batch numbers:** Not stated **Transport and storage conditions:** Not described **Person(s) performing RDT:** Performed by health workers with 3 hours training, but results confirmed by experts at the Malaria Regional Centre **RDT setting:** Health centres and mobile health units
Follow-up	Not applicable
Notes	**Source of funding:** Not stated

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	Unclear	All participants were attending malaria clinics with fever, but the sampling method was not described
Acceptable reference standard? All tests	Unclear	Microscopy was undertaken by experts at a central laboratory, but there were no details provided about the processes used
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Yes	Microscopy was undertaken at a different location than the RDTs
Index test results blinded? All tests	Yes	RDTs were undertaken at a different location than the microscopy
Uninterpretable results reported? All tests	Unclear	Number of participants enrolled in the study was explicitly stated and corresponded to the number presented in the analysis; therefore there were no withdrawals due to invalid results

Banchongaksorn 1997 (*Continued*)

Withdrawals explained? All tests	Yes	Number of participants enrolled in the study was explicitly stated and corresponded to the number presented in the analysis; therefore there were no withdrawals

Bechem 1999

Clinical features and settings	**Presenting signs and symptoms:** Fever of ≥38 °C **Previous treatment for malaria:** No exclusion criteria based on antimalarial use. Approximately 55% of the children had been given one or more antimalarial drugs between onset of symptoms and presentation at the hospital. **Clinical setting:** Paediatric Unit of Central Hospital **Country:** Cameroon (Yaounde) **Malaria endemicity:** Not stated **Malaria endemic species:** Not stated
Participants	**Sample size:** 199 **Age:** Children 2.5 months to 16 years **Sex:** Both males and females eligible. Actual proportions of males and females in the participant population not stated. **Co-morbidities and pregnancy:** No criteria based on co-morbidities. No details of the frequency of these conditions in the participant population were presented. **Parasite density of microscopy positive cases:** Range 90 to 456,000 parasites per μl, geometric mean 7620
Study design	Enrollment was consecutive and prospective. One RDT was evaluated.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy of thick and thin blood smears **Person(s) performing microscopy:** Microscopists **Microscopy setting:** Research laboratory **Number of high power fields examined before declaring negative:** 100 **Number of observer or repeats:** Two; however their method of working together was not described **Resolution of discrepancies between observers:** Not described
Index and comparator tests	**Commerical name of RDT:** ICT Malaria Pf (ICTDiagnostics, Brookvale, NSW, Australia) **Parasite(s) designed to detect:** *P. falciparum* **Designated Type:** Type 1 **Batch numbers:** Not stated **Transport and storage conditions:** Not described **Person(s) performing RDT:** Physician **RDT setting:** Paediatric unit
Follow-up	Not applicable

Bechem 1999 (*Continued*)

Notes	**Source of funding:** Not stated

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	Yes	Consecutive sample presenting to a paediatric unit with fever
Acceptable reference standard? All tests	Unclear	Although it states that there were 2 microscopists it does not mention how they were working
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Yes	Reference tests were carried out in the laboratory, RDTs were carried out in the clinic
Index test results blinded? All tests	Yes	Reference tests were carried out in the laboratory, RDTs were carried out in the clinic
Uninterpretable results reported? All tests	Yes	One participant was excluded from the analysis because their blood slide was unreadable
Withdrawals explained? All tests	Yes	One participant was excluded from the analysis because their blood slide was unreadable

Bell 2001a

Clinical features and settings	**Presenting signs and symptoms:** History of fever, headache, chills or rigors occurring within the preceding three days; or more distant history of fever or non-specific signs suggestive of malaria. **Previous treatment for malaria:** Participants who had recently taken antimalarials were not excluded; 5% of participants reported prior antimalarial use. **Clinical setting:** Village health workers in five barangaya (districts) **Country:** Philippines (Agusan del Sur Province in the northeast of the island of Maindano) **Malaria endemicity:** Generally low perennial transmission, with pockets of high transmission **Malaria endemic species:** *P. falciparum* and *P. vivax*
Participants	**Sample size:** 350 **Age:** Eligible age range not stated. Mean age of the participants was 19.5 years. **Sex:** Both males and females eligible. There were 171 male and 179 female participants. **Co-morbidities and pregnancy:** Not mentioned, either an exclusion criteria or characteristic of included participants **Parasite density of microscopy positive cases:** Not presented
Study design	Enrollment was prospective. The sampling method was not described. One RDT was evaluated.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy of thick and thin blood smears **Person(s) performing microscopy:** An experienced local microscopist for all slides; selected slides were also read by an experienced parasitologist **Microscopy setting:** Local laboratory and hospital laboratory in Australia **Number of high power fields examined before declaring negative:** 100 **Number of observer or repeats:** One, except in discordant cases where RDT and microscopy results differed, all cases RDT-positive for *P. vivax* and 20% of cases negative by slide and RDT, in which case a second reader was used **Resolution of discrepancies between observers:** The second, off-site reading was taken as the correct one
Index and comparator tests	**Commerical name of RDT:** ICT Malaria Pf/Pv (Amrad-ICT, Sydney, Australia) **Parasite(s) designed to detect:** *P. falciparum* or mixed infection, non-*falciparum* malaria species only **Designated Type:** Type 4 **Batch numbers:** Not stated **Transport and storage conditions:** Refrigerated until two weeks before use **Person(s) performing RDT:** Researchers **RDT setting:** Study villages
Follow-up	Not applicable
Notes	**Source of funding:** The Australian National Health and Medical Research Council
Table of Methodological Quality	

Bell 2001a (*Continued*)

Item	Authors' judgement	Description
Representative spectrum? All tests	Unclear	All participants had approached village health workers with symptoms suggestive of malaria, but the sampling method was not described
Acceptable reference standard? All tests	Yes	An experienced microscopist viewed at least 100 high powered fields and discordant results were re-examined
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Yes	"Slides were read by a local microscopist who was not aware of the results of the ICT tests"
Index test results blinded? All tests	Yes	RDTs were performed two to four weeks before microscopy
Uninterpretable results reported? All tests	Yes	The paper reported that there was one uninterpretable microscopy result
Withdrawals explained? All tests	Unclear	The number of participants originally enrolled in the study was not stated; therefore it is unclear whether there were any withdrawals

Bell 2001b

Clinical features and settings	**Presenting signs and symptoms:** History of fever, headache, child or rigors occurring within the preceding 3 days; or more distant history of fever or non-specific signs suggestive of malaria **Previous treatment for malaria:** Patients treated with antimalarials during the four weeks preceding the test were excluded from the analysis **Clinical setting:** Health centre in Visaya **Country:** Philippines (Agusan del Sur Province in the northeast of the island of Maindano) **Malaria endemicity:** Generally low perennial transmission, with pockets of high transmission **Malaria endemic species:** *P. falciparum* and *P. vivax*
Participants	**Sample size:** 113 **Age:** Eligible age range not stated. Mean age of the participants was 19.8 years. **Sex:** Both males and females eligible. There were 73 male and 40 female participants. **Co-morbidities and pregnancy:** Not mentioned, either as an exclusion criteria or characteristic of included participants **Parasite density of microscopy positive cases:** Not presented
Study design	Enrollment was prospective. The sampling method was not described. One RDT was evaluated.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy of thick and thin blood smears **Person(s) performing microscopy:** Not stated **Microscopy setting:** Regional Health Units **Number of high power fields examined before declaring negative:** Not stated, but probably 100 as in the other trial reported together in the same paper **Number of observer or repeats:** Not stated **Resolution of discrepancies between observers:** Not applicable
Index and comparator tests	**Commerical name of RDT:** ICT Malaria Pf/Pv (Amrad-ICT, Sydney, Australia) **Parasite(s) designed to detect:** *P. falciparum* or mixed infection, non-*falciparum* malaria species only **Designated Type:** Type 4 **Batch numbers:** Not stated **Transport and storage conditions:** Stored by barangya health workers at room temperature, averaging about 25 °C for up to six months **Person(s) performing RDT:** Barangay health workers **RDT setting:** Health centre
Follow-up	Not applicable
Notes	**Source of funding:** The Australian National Health and Medical Research Council

Table of Methodological Quality

Item	Authors' judgement	Description

Bell 2001b (*Continued*)

Representative spectrum? All tests	Unclear	All participants were attending a health centre with history of fever, headache, child or rigours within the preceding 3 days; more distant history of fever or non-specific signs suggestive of malaria; but the sampling method was not described
Acceptable reference standard? All tests	Unclear	No details given of the microscopy process
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Yes	Clear that blinding had taken place, as it was not possible to match up all the RDT and microscopy results by name and date
Index test results blinded? All tests	Yes	Clear that blinding had taken place, as it was not possible to match up all the RDT and microscopy results by name and date
Uninterpretable results reported? All tests	Yes	25 of 393 tests done were considered invalid because of an indistinct control band. Invalid results were excluded from the analysis.
Withdrawals explained? All tests	Yes	Only 113 microscopy results could be matched with RDT results by name and date; the others were lost from the analysis

Bharti 2008

Clinical features and settings	**Presenting signs and symptoms:** Fever or history of fever, and suspicion of malaria **Previous treatment for malaria:** No exclusions based on previous treatment; it was undertaken in a remote area with no medical facilities **Clinical setting:** Mobile field clinics in 10 villages **Country:** India (Remote forested region of Jabalpur during the peak monsoon season) **Malaria endemicity:** Low endemic areas with higher transmission during the monsoon **Malaria endemic species:** *P. falciparum* and *P. vivax*

Bharti 2008 (*Continued*)

Participants	**Sample size:** 291 **Age:** All age groups eligible. Actual age range of participants 1 to 60 years. **Sex:** Both males and females eligible. Male: female ratio 1:1.15. **Co-morbidities and pregnancy:** No criteria based on co-morbidities or pregnancy. No details of the frequency of these conditions in the participant population presented. **Parasite density of microscopy positive cases:** Range 80 to 111,920 parasites per cul, mean 8011, Standard Deviation 21,595
Study design	Enrollment was consecutive and prospective. One RDT was evaluated.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy thick blood films **Person(s) performing microscopy:** Experienced microscopist **Microscopy setting:** Laboratory of NIMR **Number of high power fields examined before declaring negative:** 100 **Number of observer or repeats:** One for all samples, two independent readers for samples discordant between microscopy and RDT **Resolution of discrepancies between observers:** Where the second reading gave a different result from the first, the results of the second reading were confirmed by a third examination by another technician
Index and comparator tests	**Commerical name of RDT:** First Response Combo Malaria Ag card test (Premier Medical Corporation Ltd, Mumbai, India) **Parasite(s) designed to detect:** *P. falciparum* or mixed infection, non-*falciparum* malaria species only **Designated Type:** Type 3 **Batch numbers:** 61F0107 **Transport and storage conditions:** RDTs were stored properly, at temperature of 4 °C to 30 °C, and used within their shelf life **Person(s) performing RDT:** Field laboratory assistants. Independent staff re-read the saved tests after two months and matched them with the originally recorded results **RDT setting:** Field laboratory
Follow-up	Not applicable
Notes	**Source of funding:** Indian Council of Medical Research, Delhi. Test kits provided by Premier Medical Corporation Ltd.

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	Yes	Participants were a consecutive sample of people attending mobile field clinics with fever or history of fever, and suspicion of malaria

Bharti 2008 (*Continued*)

Acceptable reference standard? All tests	Yes	An experienced microscopist viewed at least 100 high power fields before declaring a slide negative, and results discordant with RDT were independently re-examined by a second microscopist, and a third if necessary
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Yes	Microscopy was undertaken "without reference to the RDT"
Index test results blinded? All tests	Yes	RDTs were undertaken on site, and the results recorded before the microscopy results became available
Uninterpretable results reported? All tests	Yes	The paper reported that there were no invalid results
Withdrawals explained? All tests	Yes	The number of participants enrolled in the study was clearly stated, and corresponded to the number presented in the analysis; therefore there were no withdrawals

Bojang 1999

Clinical features and settings	**Presenting signs and symptoms:** Temperature of 37.5 °C or higher, or a recent history of fever **Previous treatment for malaria:** No exclusions based on previous treatment and no information presented on previous treatment, except for those with false positive results on RDT **Clinical setting:** Malaria outpatient clinic **Country:** The Gambia (Basse, Upper River Division) **Malaria endemicity:** Not stated **Malaria endemic species:** *P. falciparum*
Participants	**Sample size:** 139 **Age:** Inclusion criteria stipulated all were children; actual age range not stated **Sex:** Not mentioned either as an inclusion criteria or a characteristic of included participants **Co-morbidities and pregnancy:** Not mentioned either as an inclusion criteria or a characteristic of included participants

Bojang 1999 (*Continued*)

	Parasite density of microscopy positive cases: Not presented
Study design	Enrolment was prospective. The sampling method was not described. One RDT was evaluated.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy thick blood smear **Person(s) performing microscopy:** Not stated **Microscopy setting:** Not stated **Number of high power fields examined before declaring negative:** Not stated **Number of observer or repeats:** Not stated **Resolution of discrepancies between observers:** Not applicable
Index and comparator tests	**Commerical name of RDT:** ParaSight-F (Beckton Dickinson, Franklin Lakes, NJ, US) **Parasite(s) designed to detect:** *P. falciparum* **Designated Type:** Type I **Batch numbers:** Not stated **Transport and storage conditions:** Not stated **Person(s) performing RDT:** Field staff who had attended three training session **RDT setting:** Malaria clinic
Follow-up	Not applicable
Notes	**Source of funding:** Medical Research Council Laboratories, The Gambia

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	Unclear	All participants were attending a malaria clinic with fever or history of fever, but the sampling method was not described
Acceptable reference standard? All tests	Unclear	Not details given of the microscopy process
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Unclear	Blinding not described

Bojang 1999 (*Continued*)

Index test results blinded? All tests	Yes	"Test performed without reference to the results of the corresponding thick blood smear"
Uninterpretable results reported? All tests	Unclear	The number of participants enrolled was explicitly stated and corresponded to the number presented in the analysis; therefore there were no participants excluded due to invalid results
Withdrawals explained? All tests	Yes	The number of participants enrolled was explicitly stated and corresponded to the number presented in the analysis; therefore there were no withdrawals

Caraballo 1996

Clinical features and settings	**Presenting signs and symptoms:** Fever and suspicion of malaria **Previous treatment for malaria:** No exclusions based on previous treatment and no information presented on previous treatment, except for those with false positive results on RDT **Clinical setting:** Malaria diagnostic post **Country:** Venezuela - Bolivar state. Gold-mining area. **Malaria endemicity:** Annual parasite index 352/1000 **Malaria endemic species:** *P. falciparum*
Participants	**Sample size:** 1398 **Age:** All ages eligible; actual age range 3 months to 84 years **Sex:** Both males and females eligible: actual sample 81.2% male, 18.8% female **Co-morbidities and pregnancy:** Not mentioned, either as an inclusion criteria or characteristic of included participants **Parasite density of microscopy positive cases:** Not presented
Study design	Enrollment was prospective. The sampling method was not described. One RDT was evaluated.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy thick blood smear **Person(s) performing microscopy:** Trained malaria microscopists **Microscopy setting:** Central Headquarters of the Venezuelan Malaria Programme **Number of high power fields examined before declaring negative:** 100 **Number of observer or repeats:** Two **Resolution of discrepancies between observers:** Not stated
Index and comparator tests	**Commerical name of RDT:** ParaSight-F (Beckton Dickinson, Franklin Lakes, NJ, US) **Parasite(s) designed to detect:** *P. falciparum* **Designated Type:** Type I **Batch numbers:** Not stated

	Transport and storage conditions: Not stated **Person(s) performing RDT:** Rural visitor from the Malaria Programme **RDT setting:** Malaria diagnostic post
Follow-up	Not applicable
Notes	**Source of funding:** UNDP/World Bank/WHO-TDR (Project number 930439), Beckton Dickinson Advanced Diagostics provided the supplies to carry out this work

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	Unclear	All participants were attending diagnostics facilities with fever and suspicion of malaria, but the sampling method was not described.
Acceptable reference standard? All tests	Unclear	Two trained microscopists at a central laboratory viewed 100 high power fields before declaring negative; however it is not clear whether the microscopists worked independently of each other
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Yes	Blinding described in detail
Index test results blinded? All tests	Yes	Index test undertaken and results recorded before reference test
Uninterpretable results reported? All tests	Unclear	The number of participants originally enrolled in the study was unclear; therefore it is not possible to judge whether any were excluded from the analysis due to invalid test results
Withdrawals explained? All tests	Unclear	The number of participants originally enrolled in the study was unclear; therefore it is not possible to judge whether there were any withdrawals

Chayani 2004

Clinical features and settings	**Presenting signs and symptoms:** Specific symptoms: rigor, chills, rise of high temperature and profuse sweating; or irregular fever, joint pain and jaundice **Previous treatment for malaria:** No explicit exclusions based on previous treatment and no information presented on previous treatment. **Clinical setting:** Diagnostic and research centre (takes referrals from physicians for the diagnosis of malaria) **Country:** Orissa, India **Malaria endemicity:** Not stated **Malaria endemic species:** In sample, 78.6% *P. falciparum,* 21.4% *P. vivax*
Participants	**Sample size:** 232 **Age:** Not mentioned, either as inclusion criteria or characteristic of participants **Sex:** Not mentioned, either as inclusion criteria or characteristic of participants **Co-morbidities and pregnancy:** Not mentioned, either as inclusion criteria or characteristic of participants **Parasite density of microscopy positive cases:** Not presented
Study design	Enrollment was prospective. The sampling method was unclear. One RDT was evaluated.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy thick and thin blood smear **Person(s) performing microscopy:** Microscopists **Microscopy setting:** Diagnostic and research centre **Number of high power fields examined before declaring negative:** 200 **Number of observer or repeats:** Two independent observers **Resolution of discrepancies between observers:** A third microscopist's opinion was taken into account
Index and comparator tests	**Commerical name of RDT:** OptiMAL (DiaMed AG, Cressier, Switzerland) **Parasite(s) designed to detect:** *P. falciparum* or mixed infection, non-*falciparum* malaria species only **Designated Type:** Type 4 **Batch numbers:** Not stated **Transport and storage conditions:** Not described **Person(s) performing RDT:** Not stated **RDT setting:** Not stated
Follow-up	Not applicable
Notes	**Source of funding:** Not stated

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	Unclear	All participants were attending an ambulatory clinic with rigor, chills, rise of high temperature and profuse sweating; or irregular fever, joint pain and jaundice. However

		the sampling method was not described.
Acceptable reference standard? All tests	Yes	Two independent microscopists viewed 200 high powered fields before declaring a slide negative
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Unclear	Blinding not described
Index test results blinded? All tests	Unclear	Blinding not described
Uninterpretable results reported? All tests	Unclear	The number of participants originally enrolled in the study was not explicitly stated; therefore it is not possible to judge whether any were excluded from the analysis due to invalid test results
Withdrawals explained? All tests	Unclear	The number of participants originally enrolled in the study was not explicitly stated; therefore it is not possible to judge whether there were any withdrawals

Chitkara 2004

Clinical features and settings	**Presenting signs and symptoms:** Fever **Previous treatment for malaria:** No exclusions based on previous treatment and no information presented on previous treatment, although this data was collected as part of the study **Clinical setting:** Temporary fever treatment camp **Country:** India (Assam and Arunachal Pradesh) **Malaria endemicity:** Varied **Malaria endemic species:** mainly *P. falciparum,* some *P. vivax*
Participants	**Sample size:** 673 **Age:** All age groups eligible; actual age range not reported **Sex:** Both males and females eligible; actual proportions in the sample not reported **Co-morbidities and pregnancy:** No exclusions based on co-morbidities or pregnancy; actual frequency of these conditions in the same not reported **Parasite density of microscopy positive cases:** Not presented

Chitkara 2004 (*Continued*)

Study design	Enrollment was consecutive and prospective. One RDT was evaluated.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy thick and thin blood smear **Person(s) performing microscopy:** Chief microscopist of the District Malaria Office and two pathologists of Assam Medical College **Microscopy setting:** District Malaria Office and Assam Medical College **Number of high power fields examined before declaring negative:** Not stated **Number of observer or repeats:** All positive slides and 20% of negative slides were independently read by the pathologists from Assam Medical College **Resolution of discrepancies between observers:** Not described
Index and comparator tests	**Commerical name of RDT:** ParaHIT-F (Span diagnostics Ltd, Surat, India) **Parasite(s) designed to detect:** *P .falciparum* **Designated Type:** Type I **Batch numbers:** Not stated **Transport and storage conditions:** Not stated **Person(s) performing RDT:** Laboratory technicians **RDT setting:** Temporary fever treatment camp
Follow-up	Not applicable
Notes	**Source of funding:** Span Diagnostics provided the RDT test kits free of charge

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	Yes	Participants were a consecutive sample attending a temporary treatment camp with fever
Acceptable reference standard? All tests	Unclear	Unclear, as the numbers of high power fields viewed before declaring negative was not stated. However, the microscopy was undertaken by expert microscopists in a central malaria laboratory.
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard

Chitkara 2004 (*Continued*)

Reference standard results blinded? All tests	Yes	Two different technicians did the microscopic examination and the ParaHIT-f test and the results of their observations were compared later.
Index test results blinded? All tests	Yes	Two different technicians did the microscopic examination and the ParaHIT-f test and the results of their observations were compared later.
Uninterpretable results reported? All tests	Unclear	The number of participants originally enrolled in the study was not explicitly stated; therefore it is not possible to judge whether any were excluded from the analysis due to invalid test results
Withdrawals explained? All tests	Unclear	The number of participants originally enrolled in the study was not explicitly stated; therefore it is not possible to judge whether there were any withdrawals

Cooke 1999

Clinical features and settings	**Presenting signs and symptoms:** Fever or history of fever and a suspected diagnosis of malaria **Previous treatment for malaria:** No exclusions based on previous treatment and no information presented on previous treatment **Clinical setting:** Outpatient clinic **Country:** The Gambia (Fajara) **Malaria endemicity:** Not stated: study undertaken during period of seasonal high transmission **Malaria endemic species:** mainly *P. falciparum*
Participants	**Sample size:** 409 **Age:** Over the age of one year **Sex:** No exclusions based on sex; actual proportions of males and females in the sample not stated **Co-morbidities and pregnancy:** No exclusions based on co-morbidities or pregnancy; actual proportions with these conditions in the sample not stated **Parasite density of microscopy positive cases:** Not presented
Study design	Enrollment was consecutive and prospective. One RDT was evaluated.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy thick blood smear. Thin blood smear in the case of discordant results between RDT and blood smear. **Person(s) performing microscopy:** Experienced microscopist at the clinic laboratory. In the case of discordant results between the RDT and microscopy, a second expert

	technician at the main laboratory re-examined the slides. **Microscopy setting:** Clinic laboratory and central laboratory. **Number of high power fields examined before declaring negative:** 100 at the clinic, 500 at the main laboratory **Number of observer or repeats:** One, except in the case of discordant results, where a second observer was used **Resolution of discrepancies between observers:** Where index and reference test results were discordant the blood film at the main laboratory was read and this result used
Index and comparator tests	**Commerical name of RDT:** OptiMAL (DiaMed AG, Cressier, Switzerland) **Parasite(s) designed to detect:** *P. falciparum* or mixed infection, non-*falciparum* malaria species only **Designated Type:** Type 4 **Batch numbers:** Not stated **Transport and storage conditions:** Not described **Person(s) performing RDT:** A member of the study team **RDT setting:** Outpatient clinic
Follow-up	Not applicable
Notes	**Source of funding:** The OptiMAL assays were provided by FLOW Inc.

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	Yes	Participants were a consecutive sample of people attending an outpatient clinic with fever or a history of fever suspected to be malaria
Acceptable reference standard? All tests	Yes	All slides were examined by an experienced microscopist viewing 100 high power fields before declaring negative. Where RDT and microscopy gave discordant results, slides were re-examined by another microscopist viewing at least 500 high power fields
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard

Cooke 1999 (*Continued*)

Reference standard results blinded? All tests	Yes	The study number and laboratory number were only matched after the blood film examination and OptiMAL test had been completed
Index test results blinded? All tests	Yes	The study number and laboratory number were only matched after the blood film examination and OptiMAL test had been completed
Uninterpretable results reported? All tests	Yes	Of 409 participants recruited, one was excluded from the analysis because the test strip failed to give a results
Withdrawals explained? All tests	Yes	Of 409 participants, seven were excluded because the results were not recorded in the clinic book, and one because the index test failed to give a results

De Oliveira 2009

Clinical features and settings	**Presenting signs and symptoms:** Suspected malaria **Previous treatment for malaria:** No exclusions based on previous treatment and no information presented on previous treatment **Clinical setting:** Various health facilities including 7 hospitals, 23 health centres and 30 dispensaries **Country:** Kenya (Karicho, Bondo and Siaya Districts) **Malaria endemicity:** 30 health facilities in seasonal areas, 30 in perennial areas **Malaria endemic species:** *P. falciparum*
Participants	**Sample size:** 1827 **Age:** Five years or over **Sex:** Both males and females eligible. Actual proportions of males and females in the participant population not stated. **Co-morbidities and pregnancy:** No exclusions criteria based on co-morbidities or pregnancy. No details of the frequency of these conditions in the participant population is presented. **Parasite density of microscopy positive cases:** Not presented
Study design	Enrollment was consecutive and prospective. One RDT was evaluated.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy thick and thin blood smears **Person(s) performing microscopy:** Expert microscopists, who receive regular training at the Malaria Diagnostics and Control Centre of Excellence of the US Army Medical Research Unit in Kenya and consistently attain acceptable competency scores during such training sessions **Microscopy setting:** Malaria laboratories of the Kenya Medical Research Institute

De Oliveira 2009 (*Continued*)

	(KEMRI) and US Centres for Disease Control and Prevention (CDC) in Kisumu **Number of high power fields examined before declaring negative:** 100 **Number of observer or repeats:** Two independent observers **Resolution of discrepancies between observers:** A third microscopist, blinded to all previous blood tests, reviewed the smear
Index and comparator tests	**Commerical name of RDT:** Paracheck Pf (Orchid Biomedical Systems, Goa, India) **Parasite(s) designed to detect:** *P. falciparum* **Designated Type:** Type I **Batch numbers:** 31422 **Transport and storage conditions:** Kept at health facilities during the study. Study staff recommended that they be stored in a cool and dry place and provided thermometers to monitor daily storage temperatures. **Person(s) performing RDT:** Laboratory technicians who were trained to perform the tests according to the manufacturer's instructions **RDT setting:** Health facilities
Follow-up	Not applicable
Notes	**Source of funding:** US Centres for Disease Control and Prevention

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	Yes	Participants were a consecutive series of people attending health facilities with suspected malaria
Acceptable reference standard? All tests	Yes	Two independent expert microscopists each viewed 100 high power fields before declaring a slide negative
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Yes	Microscopists reported to be blinded to the results of the RDTs
Index test results blinded? All tests	Yes	RDTs undertaken and results recorded at the health facilities before microscopy

De Oliveira 2009 (*Continued*)

Uninterpretable results reported? All tests	Unclear	There were no withdrawals, and no reports of uninterpretable results
Withdrawals explained? All tests	Yes	Participants were excluded from the analysis if they refused to give blood samples or complete clinical information

Dev 2004

Clinical features and settings	**Presenting signs and symptoms:** Fever **Previous treatment for malaria:** No information presented on previous treatment; no suggestion of any exclusions based on previous treatment **Clinical setting:** Malaria clinics **Country:** India (Assam) **Malaria endemicity:** Mesendemic **Malaria endemic species:** *P. falciparum* and *P. vivax*
Participants	**Sample size:** 336; but varied by RDT evaluated (10 to 139) **Age:** Infants under 12 months excluded; actual age range 1 to 60 years **Sex:** Both males and females eligible. Actual proportions of males and females in the participant population not stated. **Co-morbidities and pregnancy:** No exclusion criteria based on co-morbidities or pregnancy were stated, and no details of the frequency of these conditions in the participant population is presented **Parasite density of microscopy positive cases:** Range 300 to 350,000 parasites per μl, mean 59,842, Standard Deviation 78,780
Study design	Enrollment was prospective. The sampling method was not described. Seven RDTs were evaluated; it is unclear how each RDT was allocated, as no participant received all the tests.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy thick and thin blood smears **Person(s) performing microscopy:** Technician; all positive slides and 20% of negative slides were also examined by the senior technician for confirmation of result. **Microscopy setting:** Laboratory at the malaria clinics **Number of high power fields examined before declaring negative:** 100 **Number of observer or repeats:** One in the case of most smears judged negative by the technician. Two in the case of 20% of those initially judged negative, and all those judged positive. **Resolution of discrepancies between observers:** The judgement of the senior technician was used
Index and comparator tests	**Commerical name of RDT:** Paracheck Pf (Orchid Biomedical Systems, Goa, India) ParaSight-F (Beckton Dickinson, Franklin Lakes, NJ, US) ParaHIT-F (Span diagnostics Ltd, Surat, India) ICT Malaria Pf (ICT Diagnostics, Sydney, Australia)

	New Pf-1 mini (Monozyme India Ltd, Secundrabad, India) SD Malaria Pf/Pv (SD Diagnostics Inc, Korea) Diamed OptiMAL (Flow Inc., Portland, OR, US) **Parasite(s) designed to detect:** Paracheck Pf - *P. falciparum* ParaSight-F - *P. falciparum* ParaHIT-F - *P. falciparum* ICT Malaria Pf - *P. falciparum* New Pf-1 mini - *P. falciparum* SD Malaria Pf/Pv - *P. falciparum* or mixed infection, non-*falciparum* malaria species only Diamed OptiMAL - *P. falciparum* or mixed infection, non-*falciparum* malaria species only **Designated Type:** Paracheck Pf - Type I ParaSight-F - Type I ParaHIT-F - Type I ICT Malaria Pf - Type I New Pf-1 mini - Type I SD Malaria Pf/Pv - Type 3 Diamed OptiMAL - Type 4 **Batch numbers:** Not stated **Transport and storage conditions:** Not described **Person(s) performing RDT:** The laboratory attendant performed the test and recorded his or her interpretation. The test kit result was then re-read for verification by the senior technician. **RDT setting:** Malaria clinic laboratory
Follow-up	Not applicable
Notes	**Source of funding:** Main source of funding not stated. Test kits supplied by the Government of Assam.

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	Unclear	All participants were attending malaria clinics with fever. However, during the study period, 6663 blood smears were examined, but only 336 were evaluated with RDT kits, and the sampling method for RDT evaluation was unclear.
Acceptable reference standard? All tests	Unclear	Two observers were used in the vast majority of cases; however, it is unclear whether the observers worked independently
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test

Dev 2004 (*Continued*)

Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Yes	Microscopy and RDT results were compared by an independent observer
Index test results blinded? All tests	Yes	Microscopy and RDT results were compared by an independent observer
Uninterpretable results reported? All tests	Unclear	No information presented on numbers initially allocated each RDT, so not possible to judge this
Withdrawals explained? All tests	Unclear	No information presented on numbers initially allocated each RDT, so not possible to judge this

Devi 2002

Clinical features and settings	**Presenting signs and symptoms:** Fever and referred for malaria diagnosis by physicians **Previous treatment for malaria:** No exclusions based on previous treatment and no information presented on previous treatment **Clinical setting:** Exact setting unclear, but based at M.S. Ramaiah Medical Teaching Hospital, Bangalore **Country:** India, Bangalore **Malaria endemicity:** Not stated **Malaria endemic species:** mainly *P. falciparum* some *P. vivax*
Participants	**Sample size:** 100 **Age:** All age groups eligible. Actual age structure of the study sample not described. **Sex:** Both males and females eligible. Actual proportions of males and females in the participant population not stated. **Co-morbidities and pregnancy:** No exclusions criteria based on co-morbidities or pregnancy. No details of the frequency of these conditions in the participant population is presented. **Parasite density of microscopy positive cases:** Not presented
Study design	Enrollment was random and prospective. One RDT was evaluated.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy thick and thin blood smears **Person(s) performing microscopy:** Not stated **Microscopy setting:** Large teaching hospital, in a malaria endemic area **Number of high power fields examined before declaring negative:** Not stated **Number of observer or repeats:** Not stated

Devi 2002 (*Continued*)

	Resolution of discrepancies between observers: Not applicable
Index and comparator tests	**Commerical name of RDT:** ParaHIT-f (Span Diagnostics, India) **Parasite(s) designed to detect:** *P. falciparum* **Designated Type:** Type I **Batch numbers:** Not stated **Transport and storage conditions:** Not described **Person(s) performing RDT:** Not stated **RDT setting:** Large teaching hospital, in a malaria endemic area
Follow-up	Not applicable
Notes	**Source of funding:** Not stated

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	Unclear	All participants had a fever and were referred to the study site for diagnosis of malaria; however it is unclear how participants were selected for referral
Acceptable reference standard? All tests	Unclear	No details given of the microscopy process
Partial verification avoided? All tests	Yes	All participants received both the index and the reference tests
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Unclear	Blinding not described
Index test results blinded? All tests	Unclear	Blinding not described
Uninterpretable results reported? All tests	Unclear	The number of participants originally enrolled in the study was not explicitly stated; therefore it is not possible to judge whether any were excluded from the analysis due to invalid test results
Withdrawals explained? All tests	Unclear	The number of participants originally enrolled in the study was not explicitly stated;

		therefore it is not possible to judge whether there were any withdrawals

Durrheim 1998

Clinical features and settings	**Presenting signs and symptoms:** Clinical signs and symptoms compatible with malaria **Previous treatment for malaria:** No exclusions based on previous treatment and no information presented on previous treatment **Clinical setting:** Outpatient clinic **Country:** South Africa (Lowveld region) **Malaria endemicity:** Seasonal **Malaria endemic species:** *P. falciparum*
Participants	**Sample size:** 264 **Age:** All age groups eligible. Actual age structure of the study sample not described. **Sex:** Both males and females eligible. Actual proportions of males and females in the participant population not stated. **Co-morbidities and pregnancy:** No exclusion criteria based on co-morbidities or pregnancy. No details of the frequency of these conditions in the participant population is presented. **Parasite density of microscopy positive cases:** Not presented
Study design	Enrollment was consecutive and prospective. One RDT was evaluated.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy thick blood film **Person(s) performing microscopy:** Experienced laboratory technologist **Microscopy setting:** Reference malaria laboratory **Number of high power fields examined before declaring negative:** Not stated **Number of observer or repeats:** One **Resolution of discrepancies between observers:** Not applicable
Index and comparator tests	**Commerical name of RDT:** ICT Malaria Pf (ICT Diagnostics, Sydney, Australia) **Parasite(s) designed to detect:** *P. falciparum* **Designated Type:** Type 1 **Batch numbers:** Not stated **Transport and storage conditions:** Not described **Person(s) performing RDT:** Clinic nurse checked by skilled reader **RDT setting:** Outpatient clinic
Follow-up	Not applicable
Notes	**Source of funding:** Not stated

Table of Methodological Quality

Item	**Authors' judgement**	**Description**

Durrheim 1998 (*Continued*)

Representative spectrum? All tests	Yes	Participants were a consecutive series of patients attending clinics with clinical signs and symptoms of malaria
Acceptable reference standard? All tests	No	Only one observer was used
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Yes	Microscopy was reported to be done with no prior knowledge of the results of the RDT
Index test results blinded? All tests	Yes	The RDT was reported to be performed before the microscopy results were available
Uninterpretable results reported? All tests	Unclear	The number of participants enrolled in the study is explicitly stated and corresponds to the number presented in the analysis; therefore there were no exclusions from the analysis due to invalid test results
Withdrawals explained? All tests	Yes	The number of participants enrolled in the study is explicitly stated and corresponds to the number presented in the analysis; therefore there were no withdrawals

Fernando 2004

Clinical features and settings	**Presenting signs and symptoms:** Fever or history of fever **Previous treatment for malaria:** No exclusions because of prior antimalarial use, and no data presented on the frequency of recent antimalarial use in the participants **Clinical setting:** A malaria research station and a malaria clinic **Country:** Sri Lanka **Malaria endemicity:** Not stated **Malaria endemic species:** *P. vivax* (70%) and *P. falciparum*
Participants	**Sample size:** 328 **Age:** All ages above five years eligible; mean age 28.3 years (range 5 to 72 years) **Sex:** Both males and females eligible; 64% of the participants were males **Co-morbidities and pregnancy:** No exclusion criteria based on co-morbidities or preg-

	nancy. No details of the frequency of these conditions in the participant population is presented. **Parasite density of microscopy positive cases:** Not presented
Study design	Enrollment was consecutive and prospective. One RDT was evaluated.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy thick and think blood films **Person(s) performing microscopy:** Trained microscopists **Microscopy setting:** At the clinics and in a laboratory **Number of high power fields examined before declaring negative:** 400 **Number of observer or repeats:** Two independent readers; one at the clinics and another in a laboratory **Resolution of discrepancies between observers:** There were no discrepancies between the two microscopists
Index and comparator tests	**Commerical name of RDT:** ICT Malaria Pf/Pv (Amrad-ICT, Sydney, Australia) **Parasite(s) designed to detect:** *P. falciparum* or mixed infection, non-*falciparum* malaria species only **Designated Type:** Type 2 **Batch numbers:** Not stated **Transport and storage conditions:** Stored and used at room temperature, which often exceeds 30 °C **Person(s) performing RDT:** The researchers **RDT setting:** At the clinics
Follow-up	Not applicable
Notes	**Source of funding:** National Science Foundation, Sri Lanka

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	Yes	Participants were a consecutive sample of people attending clinics with fever or history of fever
Acceptable reference standard? All tests	Yes	Twp independent trained microscopists viewed 400 high power fields before declaring a slide negative
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results

Fernando 2004 (*Continued*)

Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Unclear	Blinding not described
Index test results blinded? All tests	Unclear	Blinding not described
Uninterpretable results reported? All tests	Unclear	The number of participants enrolled was clearly stated, and the number included in the analysis corresponds to this number, indicating no withdrawals
Withdrawals explained? All tests	Yes	The number of participants enrolled was clearly stated, and the number included in the analysis corresponds to this number, indicating no withdrawals

Forney 2001

Clinical features and settings	**Presenting signs and symptoms:** Fever over 38 °C or headache or history of fever in the previous 72 hrs **Previous treatment for malaria:** Patients who were currently taking antimalarial therapy or who had been treated with antimalarial drugs within the previous two weeks were excluded **Clinical setting:** Outpatient malaria clinics **Country:** Iquitos, Peru (28% of participants); Mae Sod, Thailand (72% of participants) **Malaria endemicity:** Seasonal **Malaria endemic species:** *P. falciparum* and *P.vivax*
Participants	**Sample size:** 3006 enrolled, 2993 had blood collected, 2988 included (2162 Thailand, 838 Peru) **Age:** 15 years or over (Thailand, 72% of participants); one year or over (Peru, 28% of participants) **Sex:** Both males and females eligible. Actual proportions of males and females in the participant population not stated. **Co-morbidities and pregnancy:** No exclusion criteria based on co-morbidities or pregnancy. No details of the frequency of these conditions in the participant population is presented. **Parasite density of microscopy positive cases:** Not presented
Study design	Enrollment was consecutive and prospective. One RDT was evaluated.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy thick and thin blood film **Person(s) performing microscopy:** Trained, certified microscopist **Microscopy setting:** Malaria testing station

Forney 2001 (*Continued*)

	Number of high power fields examined before declaring negative: 200 **Number of observer or repeats:** Two independent observers **Resolution of discrepancies between observers:** A third senior microscopist examined both microscopist A's and microscopist B's slides, and gave the final judgement
Index and comparator tests	**Commerical name of RDT:** ParaSight-F (Beckton Dickinson, Franklin Lakes, NJ, US) **Parasite(s) designed to detect:** *P. falciparum* **Designated Type:** Type 1 **Batch numbers:** Not stated **Transport and storage conditions:** Not described **Person(s) performing RDT:** Trained investigator and technician, with quality control checks by the principal investigator **RDT setting:** Malaria testing station
Follow-up	Not applicable
Notes	**Source of funding:** Main funding source not stated. RDT kits provided by the manufacturer.

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	Yes	Participants were a consecutive series of people attending malaria clinics with fever over 38 °C or headache or history of fever in the previous 72 hrs
Acceptable reference standard? All tests	Yes	Two independent trained microscopists viewed at least 200 high powered fields before declaring negative
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Yes	In all cases, the results of the ParaSight-F test were determined prior to diagnostic microscopy, with strict blinding between the rapid test results and technicians performing the microscopy

Forney 2001 (*Continued*)

Index test results blinded? All tests	Yes	In all cases, the results of the ParaSight-F test were determined prior to diagnostic microscopy, with strict blinding between the rapid test results and technicians performing the microscopy
Uninterpretable results reported? All tests	Yes	Tests whose results were reported as uninterpretable after the initial procedure were repeated in an attempt to resolve the discrepant event. Repeatedly uninterpretable results were reported as such and were incorporated into calculation of sensitivity and specificity as 'false' results. There were a total of seven uninterpretable results; all were negative for *P. falciparum* by blood slide.
Withdrawals explained? All tests	Yes	There were five withdrawals after collection of blood samples; reasons were documented in all cases.

Forney 2003

Clinical features and settings	**Presenting signs and symptoms:** Fever over 38 °C or history of fever over the previous 72 h, or headaches **Previous treatment for malaria:** Patients who had taken antimalarials recently were included. No data is presented on the actual number who reported recent antimalarial use. **Clinical setting:** Outpatient malaria clinics **Country:** Thailand (Mae Sod) and Peru (Iquitos) **Malaria endemicity:** Not stated; study conducted in endemic areas during peak transmission seasons **Malaria endemic species:** *P. falciparum* and *P. vivax*
Participants	**Sample size:** 477 in Thailand, 393 in Peru **Age:** Eligibility criteria for age not stated; in practice, although younger patients were eligible, all participants were over the age of 18 **Sex:** Not mentioned, either as inclusion criteria or characteristics of participants **Co-morbidities and pregnancy:** Not mentioned, either as inclusion criteria or characteristics of participants **Parasite density of microscopy positive cases:** Not presented
Study design	Enrollment was prospective. The sampling method was not described. Three prototype RDTs were evaluated; only the most recent is presented.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy thick and thin blood smear **Person(s) performing microscopy:** Skilled, certified technicians

	Microscopy setting: Malaria testing station **Number of high power fields examined before declaring negative:** 200 **Number of observer or repeats:** Two independent observers; three for discordant slides and 5% of concordant slides **Resolution of discrepancies between observers:** A third senior microscopist examined both microscopist A's and microscopist B's slides, and gave the final judgement
Index and comparator tests	**Commerical name of RDT:** ParaSight Pf/Pv Final Prototype FV99-2 (Becton Dickinson, Franklin Lakes, NJ, USA) **Parasite(s) designed to detect:** *P. falciparum* and *P. vivax* **Designated Type:** Unknown **Batch numbers:** Not applicable (prototype) **Transport and storage conditions:** Not described **Person(s) performing RDT:** Not stated **RDT setting:** Not stated
Follow-up	Not applicable
Notes	**Source of funding:** Not stated

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	Unclear	All participants were all attending clinics with fever or headaches, but the sampling method was not described
Acceptable reference standard? All tests	Yes	Two independent, trained microscopists viewed at least 200 high power fields before declaring a slide negative
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Yes	"In all cases the results of the ParaSight Pf/Pv tests were determined prior to the completion of diagnostic microscopy"
Index test results blinded? All tests	Yes	"The technicians examining the stained smears were strictly blinded to the rapid test results"

Forney 2003 (*Continued*)

Uninterpretable results reported? All tests	Yes	Uninterpretable test results were excluded from the analysis (1 participant)
Withdrawals explained? All tests	Yes	The number of participants enrolled in the study was clearly stated, and corresponded to the number included in the analysis, with the exception of one participant not included because of uninterpretable test results

Gaye 1998

Clinical features and settings	**Presenting signs and symptoms:** Malaria symptoms **Previous treatment for malaria:** No exclusion criteria relating to prior antimalarial drug use. Data collected but only presented in the case of false positives. **Clinical setting:** Outpatient clinic **Country:** Senegal (Dakar) **Malaria endemicity:** Hypoendemic and seasonal **Malaria endemic species:** Predominantly *P. falciparum*
Participants	**Sample size:** 66 **Age:** All ages eligible. Actual age range 1 to 65 years **Sex:** Both males and females eligible. Actual proportions of males and females in the participant population 35 female, 31 male. **Co-morbidities and pregnancy:** Not mentioned **Parasite density of microscopy positive cases:** Range 500 to 86,286 parasites per μl
Study design	Enrollment was prospective. The sampling method was not described. Three RDTs were evaluated and all participants received all three tests.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy thick blood film **Person(s) performing microscopy:** Not stated **Microscopy setting:** Not stated **Number of high power fields examined before declaring negative:** Not stated **Number of observer or repeats:** Not stated **Resolution of discrepancies between observers:** Not applicable
Index and comparator tests	**Commerical name of RDT:** ICT Malaria Pf (ICT Diagnostics, Sydney, Australia) ParaSight-F (Beckton Dickinson, Franklin Lakes, NJ, US) Malaria IgG CELISA (CelLabs Sydney, Australia) (excluded as not eligible for inclusion in this review) **Parasite(s) designed to detect:** *P. falciparum* **Designated Type:** Type 1 **Batch numbers:** Not stated **Transport and storage conditions:** Not described **Person(s) performing RDT:** Not stated

Gaye 1998 (*Continued*)

	RDT setting: Not stated
Follow-up	Not applicable
Notes	**Source of funding:** Not stated

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	Unclear	All participants were presenting to an outpatient clinic with malaria symptoms, but the sampling method was not described
Acceptable reference standard? All tests	Unclear	No details given of the microscopy process
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Unclear	Blinding not described
Index test results blinded? All tests	Unclear	Blinding not described
Uninterpretable results reported? All tests	Unclear	The numbers of participants originally enrolled in the study was clearly stated, and corresponds to the number presented in the analysis; therefore there were no exclusions due to invalid test results
Withdrawals explained? All tests	Yes	The numbers of participants originally enrolled in the study was clearly stated, and corresponds to the number presented in the analysis; therefore there were no withdrawals

Gaye 1999

Clinical features and settings	**Presenting signs and symptoms:** Malaria symptoms **Previous treatment for malaria:** Not mentioned, either as an exclusion criteria or characteristic of included participants **Clinical setting:** Outpatient clinic **Country:** Senegal (North Senegal, Richard-Toll) **Malaria endemicity:** Not stated **Malaria endemic species:** Not stated
Participants	**Sample size:** 182 **Age:** All ages eligible. Actual age range 1 to 55 years **Sex:** Not mentioned, either as an inclusion criteria or characteristic of included participants **Co-morbidities and pregnancy:** Not mentioned, either as an inclusion criteria or characteristic of included participants **Parasite density of microscopy positive cases:** Not presented
Study design	Enrollment was prospective. The sampling method was not described. One test was evaluated.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy thick blood film **Person(s) performing microscopy:** Not stated **Microscopy setting:** Not stated **Number of high power fields examined before declaring negative:** Not stated **Number of observer or repeats:** Not stated **Resolution of discrepancies between observers:** Not applicable
Index and comparator tests	**Commerical name of RDT:** PATH Falciparum Malaria **Parasite(s) designed to detect:** *P. falciparum* **Designated Type:** Type 1 **Batch numbers:** Not stated **Transport and storage conditions:** Not described **Person(s) performing RDT:** Not stated **RDT setting:** Not stated
Follow-up	Not applicable
Notes	**Source of funding:** Not stated

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	Unclear	All participants were presenting to an outpatient clinic with malaria symptoms, but the sampling method was not described
Acceptable reference standard? All tests	Unclear	Not details given of the microscopy process

Gaye 1999 (*Continued*)

Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Unclear	Blinding not described
Index test results blinded? All tests	Unclear	Blinding not described
Uninterpretable results reported? All tests	Unclear	The numbers of participants originally enrolled in the study was clearly stated, and corresponds to the number presented in the analysis; therefore there were no exclusions due to invalid test results
Withdrawals explained? All tests	Yes	The numbers of participants originally enrolled in the study was clearly stated, and corresponds to the number presented in the analysis; therefore there were no withdrawals

Gerstl 2009

Clinical features and settings	**Presenting signs and symptoms:** Fever (axillary temperature >37.5 °C) or history of fever in the previous 72 h and no signs of severe disease **Previous treatment for malaria:** Not mentioned, either as an inclusion criteria or characteristic of included participants **Clinical setting:** MSF community health centre **Country:** Sierra Leone (Bo District, Eastern Sierra Leone) **Malaria endemicity:** Hyperendemic **Malaria endemic species:** *P. falciparum*
Participants	**Sample size:** 345 **Age:** Inclusion criteria 2 to 59 months **Sex:** Both males and females eligible **Co-morbidities:** No exclusions based on co-morbidities; no information presented about the frequency of co-morbid conditions in the study sample **Parasite density of microscopy positive cases:** Not presented
Study design	Enrollment was consecutive and prospective. One test was evaluated.

Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy **Person(s) performing microscopy:** Not stated **Microscopy setting:** Not stated **Number of high power fields examined before declaring negative:** Not stated **Number of observer or repeats:** Not stated **Resolution of discrepancies between observers:** Not applicable
Index and comparator tests	**Commerical name of RDT:** ParaCheck-Pf (Orchid Biomedical Systems, Goa, India) Carestart Pf/Pan **Parasite(s) designed to detect:** ParaCheck-Pf - *P. falciparum* Carestart Pf/Pan - *P. falciparum* or mixed infection, non-*falciparum* malaria species only **Designated Type:** ParaCheck-Pf - Type 1 Carestart 3 line - Type 4 **Batch numbers:** Not stated **Transport and storage conditions:** Not described **Person(s) performing RDT:** Not stated **RDT setting:** Not stated
Follow-up	Not applicable
Notes	**Source of funding:** Not stated

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	Yes	Participants were a consecutive sample of children presenting to a community health centre with fever
Acceptable reference standard? All tests	Unclear	No information was provided about the microscopy process
Partial verification avoided? All tests	Unclear	Not enough information presented to assess this
Differential verification avoided? All tests	Unclear	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Unclear	Blinding not described

Gerstl 2009 (*Continued*)

Index test results blinded? All tests	Unclear	Blinding not described
Uninterpretable results reported? All tests	Unclear	Not enough information presented to enable assessment of this
Withdrawals explained? All tests	Unclear	Not enough information presented to enable assessment of this

Ghosh 2000

Clinical features and settings	**Presenting signs and symptoms:** Febrile illness **Previous treatment for malaria:** Not mentioned, either as an inclusion criteria or characteristic of included participants **Clinical setting:** Unclear (PHC Banavara district Hassan, Karnataka) **Country:** India (Karnataka) **Malaria endemicity:** Not stated **Malaria endemic species:** Not stated
Participants	**Sample size:** 100 **Age:** Malaria cases were aged 5 years to 80 years **Sex:** Both males and females were included **Co-morbidities and pregnancy:** Not mentioned, either as an inclusion criteria or characteristic of included participants **Parasite density of microscopy positive cases:** Not presented
Study design	Enrollment was prospective. The sampling method was not described. One test was evaluated.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy thick and thin smears **Person(s) performing microscopy:** One set was immediately examined in the field while the second one was stained in the laboratory and examined carefully **Microscopy setting:** Field and laboratory (unclear which is the reference standard) **Number of high power fields examined before declaring negative:** About 200 **Number of observer or repeats:** Unclear **Resolution of discrepancies between observers:** Unclear/Not applicable
Index and comparator tests	**Commerical name of RDT:** ICT Malaria (ICT Diagnostics, Australia) **Parasite(s) designed to detect:** *P. falciparum* **Designated Type:** Type 1 **Batch numbers:** Not stated **Transport and storage conditions:** Not described **Person(s) performing RDT:** Not stated **RDT setting:** Not stated
Follow-up	Not applicable

Ghosh 2000 (*Continued*)

Notes	**Source of funding:** Not stated

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	Unclear	All participants were attending health facilities with febrile illnesses; however the exact setting was unclear, and the sampling method was not described
Acceptable reference standard? All tests	Unclear	Microscopy was undertaken under field conditions and also examined carefully in a laboratory and it was unclear which was the reference standard
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Unclear	Blinding not described
Index test results blinded? All tests	Unclear	Blinding not described
Uninterpretable results reported? All tests	Unclear	The number of participants originally enrolled in the study is not clearly stated, therefore it is unclear whether any may have been excluded from the analysis, and the reasons for this
Withdrawals explained? All tests	Unclear	The number of participants originally enrolled in the study is not clearly stated, therefore it is unclear whether any may have been withdrawn or excluded from the analysis, and the reasons for this

Guthmann 2002

Clinical features and settings	**Presenting signs and symptoms:** Clinical suspicion of malaria, diagnosed by the clinical officer **Previous treatment for malaria:** No exclusion criteria based on antimalarial use and no data collected on this **Clinical setting:** Outpatient department of a reference hospital **Country:** Mbarara, Uganda **Malaria endemicity:** Not stated **Malaria endemic species:** *P. falciparum*
Participants	**Sample size:** 742 **Age:** All age groups eligible; 315 were aged less than 5 years **Sex:** Both males and females eligible. Actual proportions of males and females in the participant population not stated **Co-morbidities and pregnancy:** No exclusions were made, and there was no information presented on pregnancy or co-morbidities **Parasite density of microscopy positive cases:** Not presented
Study design	Enrollment was consecutive and prospective. Five RDTs were tested, and most participants received all the tests.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy thick and thin blood films **Person(s) performing microscopy:** Trained malaria technician **Microscopy setting:** Not stated **Number of high power fields examined before declaring negative:** 200 **Number of observer or repeats:** One, except in the case of discordant results between microscopy and RDTs **Resolution of discrepancies between observers:** All discordant results, all slides where only gametocytes were detected and a random sample of 20% of the remaining slides were checked blind by an independent trained laboratory technician
Index and comparator tests	**Commerical name of RDTs:** Paracheck Pf dipstick (Orchid Biomedical Systems, Goa, India) Paracheck Pf device (Orchid Biomedical Systems, Goa, India) (data not included in review as duplicates Paracheck Pf dipstick) ParaHIT-f (Span diagnostics Ltd, Surat, India) (excluded as required data could not be extracted) BIO P.F (excluded as required data could not be extracted) Malaria Rapid (excluded as required data could not be extracted) **Parasite(s) designed to detect:** *P. falciparum* **Designated Type:** Type 1 **Batch numbers:** Not stated **Transport and storage conditions:** Not described **Person(s) performing RDT:** Two independent readers (persons unspecified) **RDT setting:** The research clinic
Follow-up	Not applicable

Guthmann 2002 (*Continued*)

Notes	**Source of funding:** Medicins sans Frontieres, French section. Laboratories provided the tests kits free of charge.

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	Yes	Participants were a consecutive series of people suspected to have malaria and attending an outpatient clinic
Acceptable reference standard? All tests	No	Microscopy was undertaken by trained microscopists viewing 200 high powered fields before declaring negative, but their findings were not confirmed by a second independent observer
Partial verification avoided? All tests	Yes	All participants who received the index tests also received the reference test
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Yes	Report states that the results were blind
Index test results blinded? All tests	Yes	Readers were kept blinded to the results of the microscopy examination
Uninterpretable results reported? All tests	Yes	A small number of test results (one each for Paracheck dipstick and cassette, four for paraHIT, three for BIO PF and 21 for Malaria Rapid) were invalid, and these are presented as participants missing from the analysis
Withdrawals explained? All tests	Yes	Of the 742 participants who received microscopy, 741 received Paracheck Pf, 738 received ParaHIT Pf, 739 received BIO PF and 721 received Malaria Rapid. All withdrawals after tests were given represent invalid RDTresults

Harani 2006

Clinical features and settings	**Presenting signs and symptoms:** Clinical symptoms of malaria and history of fever over 37.5 °C. People with known causes of fever other than malaria were excluded. **Previous treatment for malaria:** Patients who had been treated for malaria in the previous 4 weeks were excluded from the study **Clinical setting:** Outpatient department of a reference hospital **Country:** Pakistan **Malaria endemicity:** Not stated **Malaria endemic species:** *P. falciparum* and *P. vivax*
Participants	**Sample size:** 560 **Age:** All age groups eligible; actual age range of included participants 2 to 73 years **Sex:** Both males and females eligible. Participants included 339 males and 221 females. **Co-morbidities and pregnancy:** Not mentioned, either as an inclusion criteria or characteristic of included participants **Parasite density of microscopy positive cases:** Not presented
Study design	Enrollment was prospective. The sampling method was not described. One RDT was tested.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy thick and thin blood films **Person(s) performing microscopy:** Senior technologist and principle author **Microscopy setting:** Department of Pathology and Microbiology, Aga Khan University **Number of high power fields examined before declaring negative:** 200 **Number of observer or repeats:** Unclear, two microscopists were used but how they divided the work between them was not described **Resolution of discrepancies between observers:** Not applicable
Index and comparator tests	**Commerical name of RDT:** ICT Malaria Pf/Pv (Binax Inc., Portland, Maine, US) **Parasite(s) designed to detect:** *P. falciparum* or mixed infection, non-*falciparum* malaria species only **Designated Type:** Type 2 **Batch numbers:** Not stated **Transport and storage conditions:** Not described **Person(s) performing RDT:** The second author **RDT setting:** Microbiology section of Aga Khan University
Follow-up	Not applicable
Notes	**Source of funding:** Not stated

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	Unclear	All participants were presenting at an outpatients department with symptoms of malaria and history of fever, but the sampling method was not described

Harani 2006 (*Continued*)

Acceptable reference standard? All tests	Unclear	Two microscopists at a University laboratory viewed 200 high power fields before declaring a slide negative; however, it is unclear how the two microscopists worked together
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Yes	"The microscopists were unaware of the microscopy results"
Index test results blinded? All tests	Yes	"These results were read by the second author who was blind to the microscopy results"
Uninterpretable results reported? All tests	Unclear	The number of participants originally enrolled in the study was clearly stated, and corresponds with the number presented in the analysis; therefore there were no exclusions due to invalid results
Withdrawals explained? All tests	Yes	The number of participants originally enrolled in the study was clearly stated, and corresponds with the number presented in the analysis; therefore there were no withdrawals due to invalid results

Hopkins 2007

Clinical features and settings	**Presenting signs and symptoms:** Fever **Previous treatment for malaria:** No exclusion criteria based on antimalarial use and no data collected on this **Clinical setting:** Clinic specially set up as part of a longitudinal study, based within a main public hospital **Country:** Uganda (Kampala) **Malaria endemicity:** Not stated **Malaria endemic species:** *P. falciparum*
Participants	**Sample size:** 918 **Age:** Children aged 1.5 to 11.5 years **Sex:** Both males and females eligible. Actual proportions of males and females in the

	participant population not stated. **Co-morbidities:** No exclusions were made, and there was no information presented on co-morbidities **Parasite density of microscopy positive cases:** Not presented
Study design	Enrollment was consecutive and prospective. Two RDTs were tested, and all participants received both tests.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy thick and thin blood films **Person(s) performing microscopy:** Experienced laboratory technologists **Microscopy setting:** Hospital laboratory **Number of high power fields examined before declaring negative:** 100 **Number of observer or repeats:** Two; all smears were read a second time by study laboratory staff to confirm results **Resolution of discrepancies between observers:** Discrepant readings were resolved by a third reader
Index and comparator tests	**Commerical name of RDTs:** Paracheck Pf (Orchid Biomedical Systems, Goa, India) Parabank (Zephyr Biomedicals, Goa, India) **Parasite(s) designed to detect:** Paracheck Pf (Orchid Biomedical Systems, Goa, India) - *P. falciparum* Parabank (Zephyr Biomedicals, Goa, India) - *P. falciparum* or mixed infection, non-*falciparum* malaria species only **Designated Type:** Paracheck: Type 1 Parabank: Type 4 **Batch numbers:** Not stated **Transport and storage conditions:** Obtained directly from the manufacturer and stored in their original packaging at room temperature in the clinic. The temperature ranged from 19 °C to 29 °C over the course of the study. **Person(s) performing RDT:** Laboratory technicians. **RDT setting:** The research clinic
Follow-up	Not applicable
Notes	**Source of funding:** US National Institute of Health, with additional support from the Doris Duke Charitable Foundation

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	Yes	Participants were a consecutive series of children attending a clinic with fever in a malaria endemic area

Hopkins 2007 (*Continued*)

Acceptable reference standard? All tests	Yes	Two independent experienced microscopists viewed 100 high powered fields before declaring negative
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Yes	Microscopy was undertaken at a different location to the RDTs
Index test results blinded? All tests	Yes	Readers were unaware of the microscopy results at the time they undertook the study
Uninterpretable results reported? All tests	Unclear	The number of participants who received the tests was explicitly stated and corresponded to the number included in the analysis; therefore there were no exclusions due to invalid results
Withdrawals explained? All tests	Yes	RDTs were not performed in 15 episodes: nine at the discretion of the physician during follow-up for non-febrile illness, and six because of protocol errors

Hopkins 2008a

Clinical features and settings	**Presenting signs and symptoms:** Outpatients who had been referred to the laboratory for malaria blood smears in accordance with the usual standard of are. **Previous treatment for malaria:** No exclusion criteria based on antimalarial use and no data collected on this **Clinical setting:** Health centres **Country:** Uganda **Malaria endemicity:** 7 different sites of varying endemicity. Results not presented separately. **Malaria endemic species:** *P. falciparum*
Participants	**Sample size:** 7000 **Age:** All ages included. 3161 participants were under the age of 5 years. No separate analysis available by age. **Sex:** Both males and females eligibles. Actual proportions of males and females in the participant population not stated. **Co-morbidities and pregnancy:** No exclusions were made, and there was no informa-

	tion presented on co-morbidities or pregnancy **Parasite density of microscopy positive cases:** Not presented
Study design	Enrollment was consecutive and prospective. Two RDTs were tested, and all participants received both tests.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy thick and thin blood films **Person(s) performing microscopy:** Health centre laboratory staff and expert microscopists at a central laboratory **Microscopy setting:** Health centre staff and central hospital laboratory **Number of high power fields examined before declaring negative:** 100 **Number of observer or repeats:** Two; all smears were read by both the health centre laboratory staff and expert microscopists at the central laboratory **Resolution of discrepancies between observers:** Discrepant readings between the health centre and expert central laboratory microscopists were resolved by a second expert microscopist
Index and comparator tests	**Commerical name of RDTs:** Paracheck Pf (Orchid Biomedical Systems, Goa, India) Parabank (Zephyr Biomedicals, Goa, India) **Parasite(s) designed to detect:** Paracheck Pf - *P. falciparum* Parabank - *P. falciparum* or mixed infection, non-*falciparum* malaria species only **Designated Type:** Paracheck: Type 1 Parabank: Type 4 **Batch numbers:** Not stated **Transport and storage conditions:** Obtained directly from the manufacturer and stored in their original packaging at room temperature in the clinic. The temperature ranged from 19 °C to 31 °C over the course of the study, and relative humidity from 39% to 87%. **Person(s) performing RDT:** Study staff **RDT setting:** Health centres
Follow-up	Not applicable
Notes	**Source of funding:** US National Institute of Health, with additional support from the Doris Duke Charitable Foundation

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	Yes	All participants were referred for microscopy for suspected malaria under usual care protocols

Hopkins 2008a (*Continued*)

Acceptable reference standard? All tests	Yes	Two microscopists, including one expert microscopist at a central laboratory, read each smear. They examined 100 high powered fields before declaring negative.
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Unclear	Blinding not described
Index test results blinded? All tests	Unclear	Blinding not described
Uninterpretable results reported? All tests	Unclear	The number of participants originally enrolled in the study was clearly stated, and corresponds with the number presented in the analysis; therefore there were no exclusions due to invalid results
Withdrawals explained? All tests	Yes	The number of participants originally enrolled in the study was clearly stated, and corresponds with the number presented in the analysis; therefore there were no withdrawals due to invalid results

Hopkins 2008b

Clinical features and settings	**Presenting signs and symptoms:** Outpatients who had been referred to the laboratory for malaria blood smears in accordance with the usual standard of care **Previous treatment for malaria:** No exclusion criteria based on antimalarial use and no data collected on this **Clinical setting:** Health centres **Country:** Uganda **Malaria endemicity:** 7 different sites of varying endemicity. Results not presented separately. **Malaria endemic species:** *P. falciparum*
Participants	**Sample size:** 7000 **Age:** All ages included. 3161 participants were under the age of 5 years. **Sex:** Both males and females eligible. Actual proportions of males and females in the participant population not stated. **Co-morbidities and pregnancy:** No exclusions were made, and there was no informa-

	tion presented on co-morbidities or pregnancy **Parasite density of microscopy positive cases:** Not presented
Study design	Enrollment was consecutive and prospective. Two RDTs were tested, and all participants received both tests.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy corrected by PCR (discordant results between microscopy and RDTs were re-analysed using PCR) **Person(s) performing microscopy:** Health centre laboratory staff and expert microscopists at a central laboratory **Microscopy setting:** Health centre staff and central hospital laboratory **Number of high power fields examined before declaring negative:** 100 **Number of observer or repeats:** Two. All smears were read by both the health centre laboratory staff and expert microscopists at the central laboratory **Resolution of discrepancies between observers:** Discrepant readings between the health centre and expert central laboratory microscopists were resolved by a second expert microscopist
Index and comparator tests	**Commerical name of RDTs:** Paracheck Pf (Orchid Biomedical Systems, Goa, India) Parabank (Zephyr Biomedicals, Goa, India) **Parasite(s) designed to detect:** Paracheck Pf - *P. falciparum* Parabank - *P. falciparum* or mixed infection, non-*falciparum* malaria species only **Designated Type:** Paracheck: Type 1 Parabank: Type 4 **Batch numbers:** Not stated **Transport and storage conditions:** Obtained directly from the manufacturer and stored in their original packaging at room temperature in the clinic. The temperature ranged from 19 °C to 31 °C over the course of the study, and relative humidity from 39% to 87%. **Person(s) performing RDT:** Study staff **RDT setting:** Health centres
Follow-up	Not applicable
Notes	**Source of funding:** US National Institute of Health, with additional support from the Doris Duke Charitable Foundation

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	Yes	All participants were referred for microscopy for suspected malaria under usual care protocols

Hopkins 2008b (*Continued*)

Acceptable reference standard? All tests	Yes	Two microscopists, including one expert microscopist at a central laboratory, read each smear. They examined 100 high powered fields before declaring negative. Discordant results between expert microscopy and RDTs were then re-examined using PCR, and the PCR results taken as the 'gold standard'.
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test
Differential verification avoided? All tests	No	Discordant results between expert microscopy and RDTs were re-examined using PCR, and the PCR results taken as the 'gold standard'
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Unclear	Blinding not described
Index test results blinded? All tests	Unclear	Blinding not described
Uninterpretable results reported? All tests	Unclear	The number of participants originally enrolled in the study was clearly stated, and corresponds with the number presented in the analysis; therefore there were no exclusions due to invalid results
Withdrawals explained? All tests	Yes	The number of participants originally enrolled in the study was clearly stated, and corresponds with the number presented in the analysis; therefore there were no withdrawals due to invalid results

Iqbal 2003

Clinical features and settings	**Presenting signs and symptoms:** History of fever for 2 to 3 days and possible malaria infection **Previous treatment for malaria:** Patients with a history of antimalarial use in the previous 4 weeks were excluded **Clinical setting:** Basic health units **Country:** Pakistan (central areas of Punjab) **Malaria endemicity:** Seasonal **Malaria endemic species:** *P. falciparum* and *P. vivax*
Participants	**Sample size:** 930 **Age:** Range 2 to 55 years (not clear whether this was an inclusion criteria or characteristic of included participants) **Sex:** Not mentioned, either as an inclusion criteria or a characteristic of the participants **Co-morbidities and pregnancy:** Not mentioned, either as an inclusion criteria or a characteristic of the participants **Parasite density of microscopy positive cases:** Not presented
Study design	Enrollment was prospective. The sampling method was not described. One RDT was evaluated.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy thick blood films **Person(s) performing microscopy:** Experienced microscopist **Microscopy setting:** District Health Centre **Number of high power fields examined before declaring negative:** 200 **Number of observer or repeats:** One; however for quality assessment, 100 random slides were sent to the Microbiology Unit, University of Kuwait, for a second reading; these results were comparable to the District Health Centre results **Resolution of discrepancies between observers:** Not applicable
Index and comparator tests	**Commerical name of RDT:** OptiMAL (Flow Inc., Portland, Oregon, USA) **Parasite(s) designed to detect:** *P. falciparum* or mixed infection, non-*falciparum* malaria species only **Designated Type:** Type 4 **Batch numbers:** Not stated **Transport and storage conditions:** Not described **Person(s) performing RDT:** Laboratory staff **RDT setting:** District Health Centre
Follow-up	Not applicable
Notes	**Source of funding:** Kuwait University

Table of Methodological Quality

Item	Authors' judgement	Description

Iqbal 2003 (*Continued*)

Representative spectrum? All tests	Unclear	All participants were attending basic health units with symptoms of malaria and history of fever, but the sampling method was not described
Acceptable reference standard? All tests	No	An microscopist working at a district laboratory viewed at least 200 high power fields before declaring a slide negative; however their findings were not verified by an independent observer
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Yes	"tests were performed in a double-blind manner"
Index test results blinded? All tests	Yes	"tests were performed in a double-blind manner"
Uninterpretable results reported? All tests	Unclear	The numbers of participants originally enrolled in the study was not clearly stated, therefore it is unclear whether there were any exclusions due to invalid test results
Withdrawals explained? All tests	Unclear	The numbers of participants originally enrolled in the study was not clearly stated, therefore it is unclear whether there were any withdrawals

Kar 1998

Clinical features and settings	**Presenting signs and symptoms:** People attending a malaria clinic **Previous treatment for malaria:** No exclusion criteria based on prior antimalarial drug use; this information was recorded for each participants, but no data is presented **Clinical setting:** Malaria Clinic at a Malaria Research Centre **Country:** India (Chennai, Tamil Nadu) **Malaria endemicity:** Perennial **Malaria endemic species:** *P. falciparum* and *P. vivax*
Participants	**Sample size:** 93 **Age:** Not mentioned either as an inclusion criteria or characteristic of participants

	Sex: Not mentioned either as an inclusion criteria or characteristic of participants **Co-morbidities and pregnancy:** No information presented on co-morbidities or pregnancy **Parasite density of microscopy positive cases:** Less than 100 parasites per μl in 3 cases; between 100 and 1000 in 8 cases, over 1000 in 34 cases
Study design	Enrolment was prospective. The sampling method was not described. One RDT was tested.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy thick blood films **Person(s) performing microscopy:** Not stated **Microscopy setting:** Malaria clinic at malaria research centre **Number of high power fields examined before declaring negative:** Not stated **Number of observer or repeats:** Not stated **Resolution of discrepancies between observers:** Not applicable
Index and comparator tests	**Commerical name of RDTs:** ParaSight-F (Beckton Dickinson, Franklin Lakes, NJ, USA) **Parasite(s) designed to detect:** *P. falciparum* **Designated Type:** Type 1 **Batch numbers:** Not stated **Transport and storage conditions:** Not described **Person(s) performing RDT:** Not stated **RDT setting:** Malaria clinic at malaria research centre
Follow-up	Not applicable
Notes	**Source of funding:** Not stated

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	Unclear	All participants were attending a malaria clinic, but their symptoms were not described and the sampling method was not described
Acceptable reference standard? All tests	Unclear	Study report did not state who performed the microscopy, how many observers or repeats were used, or how many high power fields were viewed before declaring a slide negative
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test

Kar 1998 (*Continued*)

Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Unclear	Blinding not described
Index test results blinded? All tests	Unclear	Blinding not described
Uninterpretable results reported? All tests	Unclear	The numbers of participants originally enrolled in the study was not clearly stated, therefore it is unclear whether there were any exclusions due to invalid test results
Withdrawals explained? All tests	Unclear	The numbers of participants originally enrolled in the study was not clearly stated, therefore it is unclear whether there were any withdrawals

Kilian 1999

Clinical features and settings	**Presenting signs and symptoms:** Suspected uncomplicated malaria **Previous treatment for malaria:** There were no explicit exclusion criteria based on previous use of antimalarials, and no data on previous antimalarial use of the participants was presented **Clinical setting:** District malaria control programme health facilities and hospital outpatient clinic **Country:** Uganda (Kaborole District) **Malaria endemicity:** Various locations with varying endemicities **Malaria endemic species:** Mainly *P. falciparum*
Participants	**Sample size:** 1326 **Age:** Included 336 infants and 710 adults; plus 180 with ages not stated **Sex:** Included 124 pregnant women; number of other female participants was not stated **Co-morbidities and pregnancy:** Included 124 pregnant women and 586 people with previous malaria treatment failure **Parasite density of microscopy positive cases:** Not presented
Study design	Enrolment was prospective. Sampling was purposive to include mainly people of high risk groups. One RDT was tested.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy thick blood films **Person(s) performing microscopy:** Not stated **Microscopy setting:** Central malaria laboratory

	Number of high power fields examined before declaring negative: 100 **Number of observer or repeats:** At the hospital, all slides were read independently by two microscopists; at two health centres a second reading was only performed where RDT and microscopy results disagreed **Resolution of discrepancies between observers:** In the case of the second slide reading differing from the first, a third independent reading was carried out by a senior microscopist and this was considered true
Index and comparator tests	**Commerical name of RDT:** ParaSight-F (Becton Dickinson Tropical Disease Diagnostics, Sparks, MD, USA) **Parasite(s) designed to detect:** *P. falciparum* **Designated Type:** Type 1 **Batch numbers:** Not stated **Transport and storage conditions:** Not described **Person(s) performing RDT:** At the hospital, tests were carried out and read by an experienced laboratory assistant. At the health centres, the tests were carried out by health workers after training, and within one week were re-read by an experienced laboratory assistant blind to the evaluation of the health care staff. **RDT setting:** Two health units and a hospital.
Follow-up	Not applicable
Notes	**Source of funding:** The ParaSight-F tests were provided by both Becton-Dickinson and the Malaria Unit, Ministry of Health, Uganda. The study was financially supported by the Federal Ministry of Economic Cooperation and Development, Germany, through Project PN 94.2195.9. **Additional Information:** This study was part of a larger study which included a group of people who had been treated for malaria but where treatment had failed.

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	No	The majority of participants were purposively selected as members of high-risk groups (infants, pregnant women and people with treatment failure)
Acceptable reference standard? All tests	Yes	Two independent microscopists viewed at least 100 high power fields before declaring a slide negative
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results

Kilian 1999 (*Continued*)

Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Yes	RDT and microscopy undertaken at different locations
Index test results blinded? All tests	Yes	RDT and microscopy undertaken at different locations
Uninterpretable results reported? All tests	Unclear	The numbers of participants originally enrolled in the study was not clearly stated, therefore it is unclear whether there were any exclusions due to invalid test results. The text "complete data were available for 1326 patients" suggests some missing data
Withdrawals explained? All tests	Unclear	The numbers of participants originally enrolled in the study was not clearly stated, therefore it is unclear whether there were any withdrawals. The text "complete data were available for 1326 patients" suggests some missing data.

Kolaczinski 2004

Clinical features and settings	**Presenting signs and symptoms:** Suspected malaria/febrile illness **Previous treatment for malaria:** No exclusion criteria based on previous use of antimalarials, and no data on previous antimalarial use of the participants was presented **Clinical setting:** Basic health units within an Afghan refugee camp **Country:** Pakistan (North West Frontier Province) **Malaria endemicity:** Not stated **Malaria endemic species:** 80% *P. vivax,* 20% *P. falciparum*
Participants	**Sample size:** 499 **Age:** All age groups eligible for inclusion; actual age range of the participants not stated **Sex:** Both males and females eligible for inclusion; actual age range of the participants not stated **Co-morbidities and pregnancy:** No exclusions based on co-morbidities or pregnancy, and no data presented on the frequency of these conditions in the study population **Parasite density of microscopy positive cases:** Not presented
Study design	Enrollment was consecutive and prospective. One RDT was tested.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy thick and thin blood films **Person(s) performing microscopy:** Microscopists **Microscopy setting:** Basic health units within an Afghan refugee camp and HNI's reference laboratory in Peshawar

	Number of high power fields examined before declaring negative: 100 **Number of observer or repeats:** Two, one at the BHU and one at the reference laboratory **Resolution of discrepancies between observers:** Not clear, "all of the smears checked by the microscopist at each BHU were cross checked at HNI's reference laboratory at Pashawar"
Index and comparator tests	**Commerical name of RDT:** OptiMAL (DiaMed AG, Cressier, Switzerland) **Parasite(s) designed to detect:** *P. falciparum* or mixed infection, non-*falciparum* malaria species only **Designated Type:** Type 4 **Batch numbers:** Not stated **Transport and storage conditions:** Not described **Person(s) performing RDT:** Microscopists **RDT setting:** Basic health units
Follow-up	Not applicable
Notes	**Source of funding:** Not stated

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	Yes	Participants were a consecutive series of patients attending a basic health unit with suspected malaria
Acceptable reference standard? All tests	Yes	Two microscopists, one working in a central laboratory, viewed at least 100 high power fields before declaring a slide negative
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	No	The index test and reference test were undertaken by the same person
Index test results blinded? All tests	No	The index test and reference test were undertaken by the same person

Kolaczinski 2004 (*Continued*)

Uninterpretable results reported? All tests	Unclear	The number of participants originally enrolled in the study was clearly stated, and corresponded to the number presented in the analysis; therefore there were no exclusions due to invalid test results
Withdrawals explained? All tests	Yes	The number of participants originally enrolled in the study was clearly stated, and corresponded to the number presented in the analysis; therefore there were no withdrawals

Kumar 1996

Clinical features and settings	**Presenting signs and symptoms:** Febrile patients **Previous treatment for malaria:** No exclusion criteria based on prior use of antimalarials; relevant data collected but presented only for false positives **Clinical setting:** Clinic of the Malaria Research Centre **Country:** India (Goa) **Malaria endemicity:** Not stated **Malaria endemic species:** *P. vivax* and *P. falciparum*
Participants	**Sample size:** 98 **Age:** Not mentioned, either as an inclusion criteria or characteristic of included participants **Sex:** Not mentioned, either as an inclusion criteria or characteristic of included participants **Co-morbidities and pregnancy:** Not mentioned, either as an exclusion criteria or characteristic of included participants **Parasite density of microscopy positive cases:** Not presented
Study design	Enrollment was prospective. The sampling method was not described. One RDT was evaluated.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy thick and thin blood smears **Person(s) performing microscopy:** Not stated **Microscopy setting:** Clinic of the Malaria Research Centre **Number of high power fields examined before declaring negative:** Not stated **Number of observer or repeats:** Not stated **Resolution of discrepancies between observers:** Not applicable
Index and comparator tests	**Commerical name of RDTs:** ICT Malaria-Pf (ICT Diagnostics, Brookvale, NSW, Australia) **Parasite(s) designed to detect:** *P. falciparum* **Designated Type:** Type 1 **Batch numbers:** Not stated **Transport and storage conditions:** Stored at 4 °C prior to use

Kumar 1996 (*Continued*)

	Person(s) performing RDT: Not stated **RDT setting:** Clinic of the Malaria Research Centre
Follow-up	Not applicable
Notes	**Source of funding:** Not stated

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	Unclear	All participants were attending a Malaria Research Clinic with fever; however the sampling method was not described
Acceptable reference standard? All tests	Unclear	The microscopy process was not described
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Unclear	Blinding not described
Index test results blinded? All tests	Unclear	Blinding not described
Uninterpretable results reported? All tests	Unclear	The numbers of participants originally enrolled in the study was not clearly stated; therefore it is unclear whether there were any exclusions due to invalid test results
Withdrawals explained? All tests	Unclear	The numbers of participants originally enrolled in the study was not clearly stated; therefore it is unclear whether there were any withdrawals

Kumar 2004

Clinical features and settings	**Presenting signs and symptoms:** Fever **Previous treatment for malaria:** No mention of previous treatment for malaria, either as an exclusion criteria or a characteristic of included participants **Clinical setting:** Primary health centres **Country:** India (Karnataka state) **Malaria endemicity:** Not stated **Malaria endemic species:** Mainly *P. falciparum, some P. vivax*
Participants	**Sample size:** 2891 **Age:** Not mentioned either as an exclusion criteria or a characteristic of included participants **Sex:** Not mentioned either as an exclusion criteria or a characteristic of included participants **Co-morbidities and pregnancy:** Not mentioned either as an exclusion criteria or a characteristic of included participants **Parasite density of microscopy positive cases:** Not presented
Study design	Enrollment was prospective. The sampling method was not described. One RDTs was evaluated.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy thick and thin blood film **Person(s) performing microscopy:** Laboratory technicians **Microscopy setting:** Initially undertaken at the primary health centres and later cross-checked at the Central Malaria Laboratory **Number of high power fields examined before declaring negative:** Not stated **Number of observer or repeats:** Two **Resolution of discrepancies between observers:** Not described
Index and comparator tests	**Commerical name of RDT:** Paracheck-Pf (Orchid Biomedical Systems, Goa, India) **Parasite(s) designed to detect:** *P. falciparum* **Designated Type:** Type 1 **Batch numbers:** Not stated **Transport and storage conditions:** Stored at 4 °C and brought to room temperature before performing the test **Person(s) performing RDT:** Not stated **RDT setting:** Not stated
Follow-up	Not applicable
Notes	**Source of funding:** Not stated

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	Unclear	All participants were attending health centres with fever, but the sampling methods were not described

Kumar 2004 (*Continued*)

Acceptable reference standard? All tests	Unclear	Two independent microscopists read the slides; however the number of high power fields viewed before declaring a slide negative was not stated
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Unclear	Blinding not described
Index test results blinded? All tests	Unclear	Blinding not described
Uninterpretable results reported? All tests	Unclear	The numbers of participants originally enrolled in the study was not clearly stated; therefore it is unclear whether there were any exclusions due to invalid test results
Withdrawals explained? All tests	Unclear	The numbers of participants originally enrolled in the study was not clearly stated; therefore it is unclear whether there were any withdrawals

Kyabayinze 2008

Clinical features and settings	**Presenting signs and symptoms:** History of fever in the previous 24 h or axillary temperature 37.5 °C or over; no evidence of concomitant febrile illness; no danger signs or evidence of severe malaria **Previous treatment for malaria:** No exclusion criteria based on antimalarial use; data collected on prior antimalarial use but not presented for the study sample **Clinical setting:** Regional referral hospital outpatient department **Country:** Uganda **Malaria endemicity:** Hyperendemic **Malaria endemic species:** Mainly *P. falciparum*
Participants	**Sample size:** 357 **Age:** Inclusion criteria over the age of six months; 46% were under the age of five; median age 11 years (range 1 to 28 years) **Sex:** Both males and females eligible; 60% were female and 40% male **Co-morbidities and pregnancy:** People with evidence of concomitant febrile illness were excluded from the study

Kyabayinze 2008 (*Continued*)

	Parasite density of microscopy positive cases: Not presented
Study design	Enrollment was consecutive and prospective. One RDT was evaluated.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy thick and thin blood smears **Person(s) performing microscopy:** Hospital microscopists **Microscopy setting:** Hospital laboratory **Number of high power fields examined before declaring negative:** 100 **Number of observer or repeats:** Two in most cases. A third microscopist read a random 10% of slides for quality control. **Resolution of discrepancies between observers:** A third external microscopist, unaware of the first two results, resolved any discordant results
Index and comparator tests	**Commerical name of RDTs:** ICT Malaria-Pf (ICT Diagnostics, Brookvale, NSW, Australia) **Parasite(s) designed to detect:** *P. falciparum* **Designated Type:** Type 1 **Batch numbers:** Not stated **Transport and storage conditions:** Storage temperature ranged from 22 °C to 29 °C, and a single spike temperature of 38 °C was recorded during transportation **Person(s) performing RDT:** Two independent readings by trained staff **RDT setting:** Hospital laboratory
Follow-up	Not applicable
Notes	**Source of funding:** UK DFID through the COMDIS research programme consortium

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	Yes	Participants were a consecutive series of people with fever attending outpatient clinics
Acceptable reference standard? All tests	Yes	Two microscopists working in a central laboratory viewed at least 100 high power fields before declaring a slide negative
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard

Kyabayinze 2008 (*Continued*)

Reference standard results blinded? All tests	Unclear	Blinding not described
Index test results blinded? All tests	Unclear	Blinding not described
Uninterpretable results reported? All tests	Yes	7 enrolled participants were excluded due to uninterpretable blood smears
Withdrawals explained? All tests	Yes	7 enrolled participants were excluded due to uninterpretable blood smears; otherwise there were no withdrawals

Labbe 2001

Clinical features and settings	**Presenting signs and symptoms:** Fever or history of fever in the previous 24 h **Previous treatment for malaria:** Excluded if gave a history of ingestion of antimalarials in the preceding month or a history of chloroquine intolerance **Clinical setting:** Local malaria clinics run by the Laos Institute Malariology, Parasitology and Entomology **Country:** Lao PDR, Vang Vieng district of Vientiane province **Malaria endemicity:** Not stated **Malaria endemic species:** Not stated
Participants	**Sample size:** 196 **Age:** Excluded children less than one year old. No more details are given about the age presentation of the participants. **Sex:** Both males and females eligible. Actual proportions of males and females in the participant population not stated. **Co-morbidities and pregnancy:** Participants were excluded if known to be pregnant **Parasite density of microscopy positive cases:** Not presented
Study design	Enrollment was prospective. The sampling method was not described. One RDT was evaluated.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy thick and thin blood films **Person(s) performing microscopy:** Expert microscopist **Microscopy setting:** National malaria reference centre (IMPE in Vientiane) **Number of high power fields examined before declaring negative:** 100 **Number of observer or repeats:** Unclear text states "were read by expert microscopists" **Resolution of discrepancies between observers:** Not applicable or unclear
Index and comparator tests	**Commerical name of RDT:** PATH-developed dipstick **Parasite(s) designed to detect:** *P. falciparum* **Designated Type:** Type 1 **Batch numbers:** Not stated **Transport and storage conditions:** Not stated

Labbe 2001 (*Continued*)

	Person(s) performing RDT: Trained local healthcare providers **RDT setting:** Local malaria clinics
Follow-up	Not applicable
Notes	**Source of funding:** Supported in part by the Banjamin H Kean Fellowship awarded by the American Society of Tropical Medicine and Hygiene, the Bayers Healthcare/University of Toronto fellowship in Medical Microbiology, and a Career Scientist Award from the Ontorio Ministry of Health. Development of the PATH PfHRP-2 assay was funded by the United States Agency for International Development under the Technologies for Health Programme (Cooperative Agreement No. HRN-A-0096-90007).

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	Unclear	All participants were attending malaria clinic with fever symptoms, however the sampling method was unclear
Acceptable reference standard? All tests	Unclear	An expert microscopist viewed at least 100 high power fields before declaring a slide negative, however it is unclear whether their findings were conformed by a second reader
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Yes	"All testing was performed blinded to the results of the other assay"
Index test results blinded? All tests	Yes	"All testing was performed blinded to the results of the other assay"
Uninterpretable results reported? All tests	Unclear	The number of participants originally enrolled in the study was clearly stated, and corresponded to the number presented in the analysis; therefore there were no exclusions due to invalid test results

Labbe 2001 (*Continued*)

Withdrawals explained? All tests	Yes	The number of participants originally enrolled in the study was clearly stated, and corresponded to the number presented in the analysis; therefore there were no withdrawals

Mboera 2006a

Clinical features and settings	**Presenting signs and symptoms:** Fever **Previous treatment for malaria:** No exclusions based on previous treatment, and no data presented on previous use of antimalarials **Clinical setting:** Hospitals, health centres and dispensaries **Country:** Tanzania, Babati **Malaria endemicity:** Prevalence of infection varying from 1.3% in highlands to 62% in the lowlands **Malaria endemic species:** *P. falciparum*
Participants	**Sample size:** 308 **Age:** All age groups eligible. Actual age profile of participant population not presented. **Sex:** Both males and females eligible. Actual proportions of males and females in the participant population not stated. **Co-morbidities and pregnancy:** No exclusion criteria based on co-morbidities or pregnancy. No details of the frequency of these conditions in the participant population is presented. **Parasite density of microscopy positive cases:** Not presented
Study design	Enrollment was consecutive and prospective. One RDT was evaluated.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy thick and thin blood films **Person(s) performing microscopy:** Experienced microscopists **Microscopy setting:** Not stated **Number of high power fields examined before declaring negative:** 200 **Number of observer or repeats:** One **Resolution of discrepancies between observers:** Not applicable
Index and comparator tests	**Commerical name of RDT:** Paracheck Pf (Orchid Biomedical Systems, Goa, India) **Parasite(s) designed to detect:** *P. falciparum* **Designated Type:** Type 1 **Batch numbers:** Not stated **Transport and storage conditions:** Stored at 4 °C and used within one month of purchase **Person(s) performing RDT:** Local study team trained in the use of the RDT **RDT setting:** Not stated
Follow-up	Not applicable

Notes	**Source of funding:** Italian cooperation and international water management institute through the system-wide initiative in malaria and agriculture. Also the Sir Halley Stewart Trust for one author.

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	Yes	Participants were a consecutive series who had a fever and were seeking treatment for suspected malaria
Acceptable reference standard? All tests	No	An experienced microscopist viewed at least 200 high power fields before declaring a slide negative; however their results were not verified by a second, independent reader
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Yes	"The blood smears were examined by experienced microscopists who were unaware which samples had been found positive in the RDT and which negative"
Index test results blinded? All tests	Yes	"Local team member read the results independently and without knowledge of the microscopy results"
Uninterpretable results reported? All tests	Unclear	The numbers of participants originally enrolled in the study was not clearly stated, therefore it is unclear whether there were any exclusions due to invalid test results
Withdrawals explained? All tests	Unclear	The numbers of participants originally enrolled in the study was not clearly stated, therefore it is unclear whether there were any withdrawals

Mboera 2006b

Clinical features and settings	**Presenting signs and symptoms:** Fever **Previous treatment for malaria:** No exclusions based on previous treatment, and no data presented on previous use of antimalarials **Clinical setting:** Hospitals, health centres and dispensaries **Country:** Tanzania, Dodoma **Malaria endemicity:** Prevalence of infection approximately 25% **Malaria endemic species:** *P. falciparum*
Participants	**Sample size:** 88 **Age:** All age groups eligible. Actual age profile of participant population not presented. **Sex:** Both males and females eligible. Actual proportions of males and females in the participant population not stated. **Co-morbidities and pregnancy:** No exclusion criteria based on co-morbidities or pregnancy. No details of the frequency of these conditions in the participant population is presented. **Parasite density of microscopy positive cases:** Not presented
Study design	Enrollment was consecutive and prospective. One RDT was evaluated.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy thick and thin blood films **Person(s) performing microscopy:** Experienced microscopists **Microscopy setting:** Not stated **Number of high power fields examined before declaring negative:** 200 **Number of observer or repeats:** One **Resolution of discrepancies between observers:** Not applicable
Index and comparator tests	**Commerical name of RDT:** Paracheck Pf (Orchid Biomedical Systems, Goa, India) **Parasite(s) designed to detect:** *P. falciparum* **Designated Type:** Type 1 **Batch numbers:** Not stated **Transport and storage conditions:** Stored at 4 °C and used within one month of purchase **Person(s) performing RDT:** Local study team trained in the use of the RDT. **RDT setting:** Not stated
Follow-up	Not applicable
Notes	**Source of funding:** Italian cooperation and international water management institute through the system-wide initiative in malaria and agriculture. Also the Sir Halley Stewart Trust for one author.

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	Yes	Participants were a consecutive series who had a fever and were seeking treatment for suspected malaria

Mboera 2006b (*Continued*)

Acceptable reference standard? All tests	No	An experienced microscopist viewed at least 200 high power fields before declaring a slide negative; however their results were not verified by a second, independent reader
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Yes	"The blood smears were examined by experienced microscopists who were unaware which samples had been found positive in the RDT and which negative"
Index test results blinded? All tests	Yes	Local team member read the results independently and without knowledge of the microscopy results.
Uninterpretable results reported? All tests	Unclear	The numbers of participants originally enrolled in the study was not clearly stated, therefore it is unclear whether there were any exclusions due to invalid test results
Withdrawals explained? All tests	Unclear	The numbers of participants originally enrolled in the study was not clearly stated, therefore it is unclear whether there were any withdrawals

Mboera 2006c

Clinical features and settings	**Presenting signs and symptoms:** Fever **Previous treatment for malaria:** No exclusions based on previous treatment, and no data presented on previous use of antimalarials **Clinical setting:** Hospitals, health centres and dispensaries **Country:** Tanzania, Iringa **Malaria endemicity:** Prevalence of infection over 73% in the lowlands, no malaria in the highlands **Malaria endemic species:** *P. falciparum*
Participants	**Sample size:** 228 **Age:** All age groups eligible. Actual age profile of participant population not presented. **Sex:** Both males and females eligible. Actual proportions of males and females in the

	participant population not stated. **Co-morbidities and pregnancy:** No exclusion criteria based on co-morbidities or pregnancy. No details of the frequency of these conditions in the participant population is presented. **Parasite density of microscopy positive cases:** Not presented
Study design	Enrollment was consecutive and prospective. One RDT was evaluated.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy thick and thin blood films **Person(s) performing microscopy:** Experienced microscopists **Microscopy setting:** Not stated **Number of high power fields examined before declaring negative:** 200 **Number of observer or repeats:** One **Resolution of discrepancies between observers:** Not applicable
Index and comparator tests	**Commerical name of RDT:** Paracheck Pf (Orchid Biomedical Systems, Goa, India) **Parasite(s) designed to detect:** *P. falciparum* **Designated Type:** Type 1 **Batch numbers:** Not stated **Transport and storage conditions:** Stored at 4 °C and used within one month of purchase **Person(s) performing RDT:** Local study team trained in the use of the RDT **RDT setting:** Not stated
Follow-up	Not applicable
Notes	**Source of funding:** Italian cooperation and international water management institute through the system-wide initiative in malaria and agriculture. Also the Sir Halley Stewart Trust for one author.

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	Yes	Participants were a consecutive series who had a fever and were seeking treatment for suspected malaria
Acceptable reference standard? All tests	No	An experienced microscopist viewed at least 200 high power fields before declaring a slide negative; however their results were not verified by a second, independent reader
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test

Mboera 2006c (*Continued*)

Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Yes	"The blood smears were examined by experienced microscopists who were unaware which samples had been found positive in the RDT and which negative"
Index test results blinded? All tests	Yes	Local team member read the results independently and without knowledge of the microscopy results
Uninterpretable results reported? All tests	Unclear	The numbers of participants originally enrolled in the study was not clearly stated, therefore it is unclear whether there were any exclusions due to invalid test results
Withdrawals explained? All tests	Unclear	The numbers of participants originally enrolled in the study was not clearly stated, therefore it is unclear whether there were any withdrawals

Mboera 2006d

Clinical features and settings	**Presenting signs and symptoms:** Fever **Previous treatment for malaria:** No exclusions based on previous treatment, and no data presented on previous use of antimalarials **Clinical setting:** Hospitals, health centres and dispensaries **Country:** Tanzania, Muleba **Malaria endemicity:** Prevalence of infection 40% to 44% **Malaria endemic species:** *P. falciparum*
Participants	**Sample size:** 306 **Age:** All age groups eligible. Actual age profile of participant population not presented. **Sex:** Both males and females eligible. Actual proportions of males and females in the participant population not stated. **Co-morbidities and pregnancy:** No exclusion criteria based on co-morbidities or pregnancy. No details of the frequency of these conditions in the participant population is presented. **Parasite density of microscopy positive cases:** Not presented
Study design	Enrollment was consecutive and prospective. One RDT was evaluated.

Mboera 2006d (*Continued*)

Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy thick and thin blood films **Person(s) performing microscopy:** Experienced microscopists **Microscopy setting:** Not stated **Number of high power fields examined before declaring negative:** 200 **Number of observer or repeats:** One **Resolution of discrepancies between observers:** Not applicable
Index and comparator tests	**Commerical name of RDT:** Paracheck Pf (Orchid Biomedical Systems, Goa, India) **Parasite(s) designed to detect:** *P. falciparum* **Designated Type:** Type 1 **Batch numbers:** Not stated **Transport and storage conditions:** Stored at 4 °C and used within one month of purchase **Person(s) performing RDT:** Local study team trained in the use of the RDT **RDT setting:** Not stated
Follow-up	Not applicable
Notes	**Source of funding:** Italian cooperation and international water management institute through the system-wide initiative in malaria and agriculture. Also the Sir Halley Stewart Trust for one author.

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	Yes	Participants were a consecutive series who had a fever and were seeking treatment for suspected malaria
Acceptable reference standard? All tests	No	An experienced microscopist viewed at least 200 high power fields before declaring a slide negative; however their results were not verified by a second, independent reader
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Yes	"The blood smears were examined by experienced microscopists who were unaware which samples had been found positive in

Mboera 2006d (*Continued*)

		the RDT and which negative"
Index test results blinded? All tests	Yes	Local team member read the results independently and without knowledge of the microscopy results.
Uninterpretable results reported? All tests	Unclear	The numbers of participants originally enrolled in the study was not clearly stated, therefore it is unclear whether there were any exclusions due to invalid test results
Withdrawals explained? All tests	Yes	The numbers of participants originally enrolled in the study was not clearly stated, therefore it is unclear whether there were any withdrawals

Mboera 2006e

Clinical features and settings	**Presenting signs and symptoms:** Fever **Previous treatment for malaria:** No exclusions based on previous treatment, and no data presented on previous use of antimalarials **Clinical setting:** Hospitals, health centres and dispensaries **Country:** Tanzania, Mvovera **Malaria endemicity:** Prevalence of infection about 43% **Malaria endemic species:** *P. falciparum*
Participants	**Sample size:** 64 **Age:** All age groups eligible. Actual age profile of participant population not presented. **Sex:** Both males and females eligible. Actual proportions of males and females in the participant population not stated. **Co-morbidities and pregnancy:** No exclusion criteria based on co-morbidities or pregnancy. No details of the frequency of these conditions in the participant population is presented. **Parasite density of microscopy positive cases:** Not presented
Study design	Enrollment was consecutive and prospective. One RDT was evaluated.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy thick and thin blood films **Person(s) performing microscopy:** Experienced microscopists **Microscopy setting:** Not stated **Number of high power fields examined before declaring negative:** 200 **Number of observer or repeats:** One **Resolution of discrepancies between observers:** Not applicable
Index and comparator tests	**Commerical name of RDT:** Paracheck Pf (Orchid Biomedical Systems, Goa, India) **Parasite(s) designed to detect:** *P. falciparum* **Designated Type:** Type 1

Mboera 2006e (*Continued*)

	Batch numbers: Not stated **Transport and storage conditions:** Stored at room temperature for 12 months **Person(s) performing RDT:** Local study team trained in the use of the RDT **RDT setting:** Not stated
Follow-up	Not applicable
Notes	**Source of funding:** Italian cooperation and international water management institute through the system-wide initiative in malaria and agriculture. Also the Sir Halley Stewart Trust for one author.

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	Yes	Participants were a consecutive series who had a fever and were seeking treatment for suspected malaria
Acceptable reference standard? All tests	No	An experienced microscopist viewed at least 200 high power fields before declaring a slide negative; however their results were not verified by a second, independent reader
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Yes	"The blood smears were examined by experienced microscopists who were unaware which samples had been found positive in the RDT and which negative"
Index test results blinded? All tests	Yes	Local team member read the results independently and without knowledge of the microscopy results
Uninterpretable results reported? All tests	Unclear	The numbers of participants originally enrolled in the study was not clearly stated, therefore it is unclear whether there were any exclusions due to invalid test results

Mboera 2006e (*Continued*)

Withdrawals explained? All tests	Unclear	The numbers of participants originally enrolled in the study was not clearly stated, therefore it is unclear whether there were any withdrawals

Mekonnen 2010

Clinical features and settings	**Presenting signs and symptoms:** Febrile, clinically suspected for malaria **Previous treatment for malaria:** No exclusions based on previous treatment, and no relevant data presented **Clinical setting:** Outpatient department of a health centre **Country:** Ethiopia (Jimma, South-West), 300 km south-west of Addis Ababa, 1760 m above sea level **Malaria endemicity:** Not stated: transmission takes place throughout the year **Malaria endemic species:** *P. falciparum* and *P. vivax*
Participants	**Sample size:** 240 **Age:** Eligible age range not stated. Actual age range of participants was 1 to 60 years, with a mean age of 25 years **Sex:** Both males and females eligible: 57.5% of the study participants were male, 42.5% female **Co-morbidities and pregnancy:** Not mentioned, either as an exclusion criteria or characteristic of the included participants **Parasite density of microscopy positive cases:** Not presented
Study design	Enrollment was prospective. The sampling method was not described. One RDT was evaluated.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy thick and thin blood films **Person(s) performing microscopy:** Experienced malaria technicians **Microscopy setting:** Not stated **Number of high power fields examined before declaring negative:** 300 **Number of observer or repeats:** Discordant results between RDTs and slides were repeated **Resolution of discrepancies between observers:** Not described
Index and comparator tests	**Commerical name of RDT:** CareStart Malaria Pf/Pv Combo (Access Bio Inc, Monmouth Junction, New Jersey, USA) **Parasite(s) designed to detect:** *P. falciparum* and *P. vivax* **Designated Type:** Type 5 **Batch numbers:** Not stated **Transport and storage conditions:** Stored according to the guidelines of the manufacturer and quality of package desiccant was checked before use **Person(s) performing RDT:** Experienced malaria technicians **RDT setting:** Not stated
Follow-up	Not applicable

Notes	**Source of funding:** Recieved financial support from the School of Laboratory Studies of the Jimma Univeristy and the VLIR-IUC program between Flanders and Jimma Univeristy. Access Bio Ltd donated the CareStart Malaria Pf/Pv Combo test kit.

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	Unclear	All participants were attending a clinic with fever and suspected malaria, but the sampling method was not described
Acceptable reference standard? All tests	Yes	Experienced technicians independently viewed 300 high power fields before declaring a slide negative. Discordant results were repeated independently.
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Yes	Blinding not described
Index test results blinded? All tests	Yes	"Results of the CareStart tests were determined prior to microscopic results with strict blinding to the microscopic examination of the blood film"
Uninterpretable results reported? All tests	Unclear	The number of participants originally enrolled in the study was clearly stated, and corresponded to the number presented in the analysis; therefore there were no exclusions due to invalid test results
Withdrawals explained? All tests	Yes	The number of participants originally enrolled in the study was clearly stated, and corresponded to the number presented in the analysis; therefore there were no withdrawals

Mendiratta 2006

Clinical features and settings	**Presenting signs and symptoms:** Clinically suspected to be suffering from malaria **Previous treatment for malaria:** No exclusions based on previous treatment, and no data presented on previous use of antimalarials, except for retrospective analysis in the case of false positive results **Clinical setting:** Not clear **Country:** Sevagram, India **Malaria endemicity:** Not stated **Malaria endemic species:** *P. falciparum*
Participants	**Sample size:** 443 **Age:** Age profile of participant population not presented. Does not mention age as inclusion criteria. **Sex:** Both males and females eligible. Actual proportions of males and females in the participant population not stated. **Co-morbidities and pregnancy:** No exclusion criteria based on co-morbidities or pregnancy. No details of the frequency of these conditions in the participant population presented. **Parasite density of microscopy positive cases:** Not presented
Study design	Enrollment was consecutive and prospective. One RDT was evaluated.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy thick and thin blood films **Person(s) performing microscopy:** Experienced microscopists **Microscopy setting:** Department of Microbiology, Mahatma Ghandi Institute of Medical Sciences, Sevagram **Number of high power fields examined before declaring negative:** Not stated **Number of observer or repeats:** Two independent observers **Resolution of discrepancies between observers:** Not described
Index and comparator tests	**Commerical name of RDT:** Paracheck Pf (Orchid Biomedical Systems, Goa, India) **Parasite(s) designed to detect:** *P. falciparum* **Designated Type:** Type 1 **Batch numbers:** Not stated **Transport and storage conditions:** Not described **Person(s) performing RDT:** Not stated **RDT setting:** Department of Microbiology, Mahatma Ghandi Institute of Medical Sciences, Sevagram
Follow-up	Not applicable
Notes	**Source of funding:** Not stated

Table of Methodological Quality

Item	**Authors' judgement**	**Description**

Mendiratta 2006 (*Continued*)

Representative spectrum? All tests	Unclear	Participants were a consecutive sample of people with fever and clinically suspected malaria; however the setting is unclear
Acceptable reference standard? All tests	Unclear	Microscopy undertaken by two trained microscopists, but it is was not stated how many high power fields they viewed before declaring a slide negative
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Unclear	Blinding not described
Index test results blinded? All tests	Unclear	Blinding not described
Uninterpretable results reported? All tests	Unclear	The number of participants originally enrolled in the study was clearly stated, and corresponded to the number presented in the analysis; therefore there were no exclusions due to invalid test results
Withdrawals explained? All tests	Yes	The number of participants originally enrolled in the study was clearly stated, and corresponded to the number presented in the analysis; therefore there were no withdrawals

Mens 2007a

Clinical features and settings	**Presenting signs and symptoms:** Suspected uncomplicated malaria, fever or history of fever in the previous 24 h **Previous treatment for malaria:** No exclusions based on previous treatment, and no data presented on previous use of antimalarials **Clinical setting:** Health centre **Country:** Tanzania **Malaria endemicity:** Hypoendemic **Malaria endemic species:** *P. falciparum*

Mens 2007a (*Continued*)

Participants	**Sample size:** 154 **Age:** 6 months to 12 years **Sex:** Both males and females eligible; Male:female ratio 1.8:1 **Co-morbidities and pregnancy:** No exclusion criteria based on co-morbidities. No details of the frequency of these conditions in the participant population is presented. **Parasite density of microscopy positive cases:** 3 cases: 160, 120 and 1000 parasites per μl
Study design	Enrollment was consecutive and prospective. Three RDTs were tested. All individuals received all three tests.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy thick and thin blood films **Person(s) performing microscopy:** Experienced microscopists **Microscopy setting:** Not stated **Number of high power fields examined before declaring negative:** Not stated. Parasite density was counted against 200 leukocytes. **Number of observer or repeats:** Two **Resolution of discrepancies between observers:** Report stated that there were no discordant results between the two microscopists
Index and comparator tests	**Commerical name of RDT:** Paracheck Pf (Orchid Biomedical Systems, Goa, India) OptiMAL (Diamed AG, Switzerland) - *P. falciparum* or mixed infection, non-*falciparum* malaria species only **Parasite(s) designed to detect:** Paracheck Pf - *P. falciparum* OptiMAL - *P. falciparum* or mixed infection, non-*falciparum* malaria species only **Designated Type:** Paracheck Pf - Type 1 OptiMAL - Type 4 **Batch numbers:** Not stated **Transport and storage conditions:** Not described **Person(s) performing RDT:** Two independent readers **RDT setting:** Not mentioned
Follow-up	Not applicable
Notes	**Source of funding:** The Hubrecht-Janssen Fund, KIT, Amsterdam, Netherlands

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	Yes	Participants were a consecutive sample of children with fever or history of fever in the past 24 h

Mens 2007a (*Continued*)

Acceptable reference standard? All tests	Unclear	Two independent microscopists examined the slides. Unclear how many high power fields were examined before declaring a slide negative.
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Yes	Report states that microscopists were blinded to the results of the others tests performed
Index test results blinded? All tests	Yes	Report states that readers were blinded to the results of the other tests performed
Uninterpretable results reported? All tests	Yes	Paracheck: 4 failures; OptiMAL: 4 failures
Withdrawals explained? All tests	No	Unclear whether test failures were repeated, or whether they were included or excluded in the analysis

Mens 2007b

Clinical features and settings	**Presenting signs and symptoms:** Suspected uncomplicated malaria, fever or history of fever in the previous 24 h **Previous treatment for malaria:** No exclusions based on previous treatment, and no data presented on previous use of antimalarials **Clinical setting:** Hospital outpatients **Country:** Kenya **Malaria endemicity:** Mesoendemic **Malaria endemic species:** *P. falciparum*
Participants	**Sample size:** 184 **Age:** 6 months to 12 years **Sex:** Both males and females eligible; male: female ratio 1:1 **Co-morbidities and pregnancy:** No exclusions based on co-morbidities. No details of the frequency of these conditions in the participant population presented. **Parasite density of microscopy positive cases:** Range 400 to 828,800 parasites per μl, mean 18,680

Mens 2007b (*Continued*)

Study design	Enrollment was consecutive and prospective. Three RDTs were tested. All individuals received all three tests.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy thick and thin blood films **Person(s) performing microscopy:** Experienced microscopists **Microscopy setting:** Not stated **Number of high power fields examined before declaring negative:** Not stated. Parasite density was counted against 200 leukocytes. **Number of observer or repeats:** Two **Resolution of discrepancies between observers:** Report stated that there were no discordant results between the two microscopists
Index and comparator tests	**Commerical name of RDT:** Paracheck Pf (Orchid Biomedical Systems, Goa, India) OptiMAL (Diamed AG, Switzerland) Parascreen (Zephyr Biomedical, Verna, Goa, India) **Parasite(s) designed to detect:** Paracheck Pf - *P. falciparum* OptiMAL - *P. falciparum* or mixed infection, non-*falciparum* species only Parascreen - *P. falciparum* or mixed infection, non-*falciparum* species only **Designated Type:** Paracheck Pf - Type 1 OptiMAL - Type 4 Parascreen - Type 3 **Batch numbers:** Not stated **Transport and storage conditions:** Not described **Person(s) performing RDT:** Two independent readers **RDT setting:** Not mentioned
Follow-up	Not applicable
Notes	**Source of funding:** The Hubrecht-Janssen Fund, KIT, Amsterdam, Netherlands

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	Yes	Participants were a consecutive sample of children with fever or history of fever in the past 24 h
Acceptable reference standard? All tests	Unclear	Two independent microscopists examined the slides. Unclear how many high power fields were examined before declaring a slide negative.

Mens 2007b (*Continued*)

Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Yes	Report states that microscopists were blinded to the results of the other tests performed
Index test results blinded? All tests	Yes	Report states that readers were blinded to the results of the other tests performed
Uninterpretable results reported? All tests	Yes	Paracheck: 4 failures; OptiMAL: 5 failures; Parascreen: 1 failure
Withdrawals explained? All tests	No	Unclear whether test failures were repeated, or whether they were included or excluded in the analysis

Mharakurwa 1997a

Clinical features and settings	**Presenting signs and symptoms:** Clinical symptoms of malaria **Previous treatment for malaria:** No exclusions based on previous treatment, and no data presented on previous use of antimalarials, although this data was collected as part of the study **Clinical setting:** Primary health care centres **Country:** Hurungwe, Zimbabwe **Malaria endemicity:** Hyperendemic **Malaria endemic species:** *P. falciparum*
Participants	**Sample size:** 136 **Age:** All age groups eligible. Actual age structure of the study sample not stated. **Sex:** Both males and females eligible. Actual ratio of males and females not stated. **Co-morbidities and pregnancy:** No exclusion criteria based on co-morbidities. No details of the frequency of these conditions in the participant population is presented. **Parasite density of microscopy positive cases:** Geometric mean 52 parasites per μl
Study design	Enrollment was consecutive and prospective. One RDT was tested.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy thick and thin blood films **Person(s) performing microscopy:** Not stated **Microscopy setting:** Not stated **Number of high power fields examined before declaring negative:** 100

Mharakurwa 1997a (*Continued*)

	Number of observer or repeats: Not stated **Resolution of discrepancies between observers:** Not applicable
Index and comparator tests	**Commerical name of RDT:** ParaSight-F (Beckton Dickinson, Franklin Lakes, NJ, USA) **Parasite(s) designed to detect:** *P. falciparum* **Designated Type:** Type 1 **Batch numbers:** Not stated **Transport and storage conditions:** Not described **Person(s) performing RDT:** Nurses who had been trained to use the test **RDT setting:** Primary health care centre
Follow-up	Not applicable
Notes	**Source of funding:** Not stated

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	Yes	Participants were a consecutive sample of people attending health centres with clinical symptoms of malaria
Acceptable reference standard? All tests	Unclear	It is unclear how many observer repeats were done, who did the microscopy and where the microscopy was done. However, it is clear that 100 high power fields were viewed before declaring a slide negative.
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Yes	Microscopy was undertaken at a different site to the RDTs
Index test results blinded? All tests	Yes	RDTs were undertaken and the results recorded on-site before microscopy was done off-site
Uninterpretable results reported? All tests	Unclear	The numbers of participants originally enrolled in the study was not clearly stated, therefore it is unclear whether there were any exclusions due to invalid test results

Mharakurwa 1997a (*Continued*)

Withdrawals explained? All tests	Unclear	The numbers of participants originally enrolled in the study was not clearly stated, therefore it is unclear whether there were any withdrawals

Mharakurwa 1997b

Clinical features and settings	**Presenting signs and symptoms:** Clinical symptoms of malaria **Previous treatment for malaria:** No exclusions based on previous treatment, and no data presented on previous use of antimalarials, although this data was collected as part of the study **Clinical setting:** Primary health care centres **Country:** Mutasa, Zimbabwe **Malaria endemicity:** Mesoendemic **Malaria endemic species:** *P. falciparum*
Participants	**Sample size:** 96 **Age:** All age groups eligible. Actual age structure of the study sample not described. **Sex:** Both males and females eligible. Actual ratio of males and females not described. **Co-morbidities and pregnancy:** No exclusion criteria based on co-morbidities. No details of the frequency of these conditions in the participant population is presented. **Parasite density of microscopy positive cases:** Geometric mean 188 parasites per μl
Study design	Enrollment was consecutive and prospective. One RDT was tested.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy thick and thin blood films **Person(s) performing microscopy:** Not stated **Microscopy setting:** Not stated **Number of high power fields examined before declaring negative:** 100 **Number of observer or repeats:** Not stated **Resolution of discrepancies between observers:** Not applicable
Index and comparator tests	**Commerical name of RDT:** ParaSight-F (Beckton Dickinson, Franklin Lakes, NJ, USA) **Parasite(s) designed to detect:** *P. falciparum* **Designated Type:** Type 1 **Batch numbers:** Not stated **Transport and storage conditions:** Not described **Person(s) performing RDT:** Nurses who had been trained to use the test **RDT setting:** Primary health care centre
Follow-up	Not applicable
Notes	**Source of funding:** Not stated

Table of Methodological Quality

Mharakurwa 1997b (*Continued*)

Item	Authors' judgement	Description
Representative spectrum? All tests	Yes	Participants were a consecutive sample of people attending health centres with clinical symptoms of malaria
Acceptable reference standard? All tests	Unclear	It is unclear how many observer repeats were done, who did the microscopy and where the microscopy was done. However, it is clear that 100 high power fields were viewed before declaring a slide negative.
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Yes	Microscopy was undertaken at a different site to the RDTs
Index test results blinded? All tests	Yes	RDTs were undertaken and the results recorded on-site before microscopy was done off-site
Uninterpretable results reported? All tests	Unclear	The numbers of participants originally enrolled in the study was not clearly stated, therefore it is unclear whether there were any exclusions due to invalid test results
Withdrawals explained? All tests	Unclear	The numbers of participants originally enrolled in the study was not clearly stated, therefore it is unclear whether there were any withdrawals

Mharakurwa 1997c

Clinical features and settings	**Presenting signs and symptoms:** Specimens sent to the Public Health Laboratory for malaria diagnosis **Previous treatment for malaria:** No exclusions based on previous treatment, and no data presented on previous use of antimalarials, although this data was collected as part of the study **Clinical setting:** Primary health care centres **Country:** Harare, Zimbabwe **Malaria endemicity:** Hypoendemic **Malaria endemic species:** *P. falciparum*
Participants	**Sample size:** 213 **Age:** All age groups eligible. Actual age structure of the study sample not described. **Sex:** Both males and females eligibles. Actual ratio of males and females not described. **Co-morbidities and pregnancy:** No exclusion criteria based on co-morbidities. No details of the frequency of these conditions in the participant population is presented. **Parasite density of microscopy positive cases:** Geometric mean 2 parasites per μl
Study design	Enrollment was consecutive and prospective. One RDT was tested.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy thick and thin blood films **Person(s) performing microscopy:** Not stated **Microscopy setting:** Not stated **Number of high power fields examined before declaring negative:** 100 **Number of observer or repeats:** Not stated **Resolution of discrepancies between observers:** Not applicable
Index and comparator tests	**Commerical name of RDT:** ParaSight-F (Beckton Dickinson, Franklin Lakes, NJ, US) **Parasite(s) designed to detect:** *P. falciparum* **Designated Type:** Type 1 **Batch numbers:** Not stated **Transport and storage conditions:** Not described **Person(s) performing RDT:** Nurses who had been trained to use the test **RDT setting:** Primary health care centre
Follow-up	Not applicable
Notes	**Source of funding:** Not stated

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	Unclear	Participants included all people who had a blood sample sent to the Public Health Laboratory for diagnosis of malaria - the criteria for referral is unclear

Mharakurwa 1997c (*Continued*)

Acceptable reference standard? All tests	Unclear	It is unclear how many observer repeats were done, who did the microscopy and where the microscopy was done. However, it is clear that 100 high power fields were viewed before declaring a slide negative.
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Yes	Microscopy was undertaken at a different site to the RDTs
Index test results blinded? All tests	Yes	RDTs were undertaken and the results recorded on-site before microscopy was done off-site
Uninterpretable results reported? All tests	Unclear	The numbers of participants originally enrolled in the study was not clearly stated; therefore it is unclear whether there were any exclusions due to invalid test results
Withdrawals explained? All tests	Unclear	The numbers of participants originally enrolled in the study was not clearly stated; therefore it is unclear whether there were any withdrawals

Mohapatra 1996

Clinical features and settings	**Presenting signs and symptoms:** Clinical symptoms of malaria **Previous treatment for malaria:** No exclusions based on previous treatment, and no data presented on previous use of antimalarials, although this data was collected as part of the study **Clinical setting:** Malaria clinics set up in the field **Country:** India, Assam **Malaria endemicity:** Highly endemic **Malaria endemic species:** Mainly *P. falciparum*
Participants	**Sample size:** 100 **Age:** All age groups eligible; actual age range of the participants not reported **Sex:** Both males and females eligible; numbers of male and female participants not reported **Co-morbidities and pregnancy:** No exclusion criteria based on pregnancy or comor-

Mohapatra 1996 (*Continued*)

	bidity, and no relevant data presented for the included participants **Parasite density of microscopy positive cases:** Not presented
Study design	Enrollment was random and prospective. One RDT was tested.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy thick and thin blood films **Person(s) performing microscopy:** Not stated **Microscopy setting:** Malaria clinic set up in the field **Number of high power fields examined before declaring negative:** Not stated **Number of observer or repeats:** Not stated **Resolution of discrepancies between observers:** Not applicable
Index and comparator tests	**Commerical name of RDT:** ICT Malaria Pf (ICT Diagnostics, Sydney, Australia) **Parasite(s) designed to detect:** *P. falciparum* **Designated Type:** Type 1 **Batch numbers:** Not stated **Transport and storage conditions:** Not described **Person(s) performing RDT:** Not stated **RDT setting:** Malaria clinic set up in the field
Follow-up	Not applicable
Notes	**Source of funding:** Not stated

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	Yes	All participants were a random sample of people attending malaria clinics with clinical symptoms of malaria.
Acceptable reference standard? All tests	Unclear	There is no information presented on who performed the test, the number of observers, or the number of high power fields viewed before declaring a slide negative
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Unclear	Blinding not described

Mohapatra 1996 (*Continued*)

Index test results blinded? All tests	Unclear	Blinding not described
Uninterpretable results reported? All tests	Unclear	The number of participants enrolled in the study was clearly stated, and corresponded to the number presented in the analysis, therefore there were no exclusions due to invalid test results
Withdrawals explained? All tests	Yes	The number of participants enrolled in the study was clearly stated, and corresponded to the number presented in the analysis, therefore there were no withdrawals

Moonasar 2009

Clinical features and settings	**Presenting signs and symptoms:** Fever or headache or chills **Previous treatment for malaria:** Patients who had recent malaria or had recently been on malaria treatment were excluded **Clinical setting:** Clinics **Country:** South Africa (Vhembe district, Limpopo province) **Malaria endemicity:** Not stated. The study was conducted during the high-transmission season in an area chosen because it had the highest incidence of malaria in the province for the previous nine years. **Malaria endemic species:** Mainly *P. falciparum*
Participants	**Sample size:** 405 **Age:** All ages eligible for inclusion; actual age range was 1 to 81 years, median 24.5 years **Sex:** Both males and females eligible for inclusion; 56% of included participants were male **Co-morbidities and pregnancy:** Severely ill patients needing referral; patients with an obvious non-malarial fever and pregnant women were excluded **Parasite density of microscopy positive cases:** Range 440 to >20,000 parasites per μl. Median 25,680.
Study design	Enrollment was consecutive and prospective. One RDT was tested.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy thick and thin blood films **Person(s) performing microscopy:** Specialised malaria microscopists **Microscopy setting:** Health Centre **Number of high power fields examined before declaring negative:** 100 (stated that "standard techniques" were used and gave an appropriate reference) **Number of observer or repeats:** Two independent readers **Resolution of discrepancies between observers:** In the case of discordant results between microscopy and RDT, a medical technologist at the Limpopo Department of Health reference centre who was highly skilled in malaria microscopy and blinded to previous results re-read the slides. This result was taken to be correct.

Index and comparator tests	**Commerical name of RDT:** ICT Malaria Pf (ICT Diagnostics, Sydney, Australia) **Parasite(s) designed to detect:** *P. falciparum* **Designated Type:** Type 1 **Batch numbers:** Not stated **Transport and storage conditions:** Not described **Person(s) performing RDT:** Nurses trained in RDT testing **RDT setting:** Outpatient clinic
Follow-up	Not applicable
Notes	**Source of funding:** Ernest Oppenheimer Trust provided financial assistance in conducting the study

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	Yes	Participants were a consecutive series of people attending a health centre with fever, headache or chills
Acceptable reference standard? All tests	Yes	Two experienced microscopists (3 in the case of discordant results between microscopy and RDT) independently viewed at least 100 high power fields before declaring a slide negative
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Yes	The microscopists were blinded to the RDT results and read the thin and thick films independently
Index test results blinded? All tests	Yes	RDTs were carried out first and result recorded by the nurse at the clinic
Uninterpretable results reported? All tests	Unclear	The number enrolled is clearly stated and corresponds to the number included in the analysis; therefore we can assume that there were no exclusions due to invalid results

Withdrawals explained? All tests	Yes	The number enrolled is clearly stated and corresponds to the number included in the analysis; therefore we can assume that there were no withdrawals

Msellem 2009

Clinical features and settings	**Presenting signs and symptoms:** Fever in the previous 24 h and symptoms compatible with uncomplicated malaria **Previous treatment for malaria:** No exclusions based on previous antimalarial use, and no data presented for the study sample **Clinical setting:** Four primary health care units **Country:** Zanzibar (Muyuno and Uzini on Unguja Island and Kinyasini and Mzambarauni on Pemba Island) **Malaria endemicity:** Recorded parasite rates between 10% and 50% in different age groups. The four study sites aimed to provide a representative picture of Zanzibar with regard to malaria epidemiology. The study was conducted during both the low transmission and high transmission seasons. **Malaria endemic species:** *P. falciparum*
Participants	**Sample size:** 1005 were allocated to receive RDTs **Age:** All ages eligible for inclusion; 55% of participants were under the age of five years **Sex:** Both males and females eligible for inclusion; actual proportions of males and females in the study sample not stated **Co-morbidities and pregnancy:** There were no exclusions based on co-morbidities or pregnancy; and no data presented on the frequency of these conditions in the study participants **Parasite density of microscopy positive cases:** Geometric mean 3840 parasites per μl, range 10 to 457,236, 95% CI 3150 to 4681
Study design	Enrollment into the study was consecutive and participants were allocated to receive RDTs according to the week of the study (quasi-randomly). Enrollment was prospective. One RDT was tested.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy thick blood films **Person(s) performing microscopy:** Qualified microscopists **Microscopy setting:** Central laboratory **Number of high power fields examined before declaring negative:** 100 **Number of observer or repeats:** Two independent readers **Resolution of discrepancies between observers:** Examined by the third reader (decision rule not stated)
Index and comparator tests	**Commerical name of RDT:** ParaCheck-Pf (Orchid Biomedical Systems, India) **Parasite(s) designed to detect:** *P. falciparum* **Designated Type:** Type 1 **Batch numbers:** Not stated **Transport and storage conditions:** Not described

	Person(s) performing RDT: Nurses trained in RDT testing **RDT setting:** Outpatient clinic
Follow-up	Not applicable
Notes	**Source of funding:** Not stated

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	Yes	Participants were consecutively sampled from people attending clinic with fever in the previous 24 h and with symptoms compatible with uncomplicated malaria
Acceptable reference standard? All tests	Yes	Two independent microscopists working in a central laboratory viewed 100 high power field before declaring a slide negative
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Yes	The microscopy was undertaken at a different location to the RDTs
Index test results blinded? All tests	Yes	RDTs were undertaken and results recorded before the microscopy results became available
Uninterpretable results reported? All tests	Unclear	There were no reports of any uninterpretable results, and the number enrolled was clearly stated and corresponds with the number presented in the analysis
Withdrawals explained? All tests	Yes	There were no withdrawals; the number enrolled in the study was clearly stated and corresponds with the number presented in the analysis

Murahwa 1999

Clinical features and settings	**Presenting signs and symptoms:** Clinical signs and symptoms associated with malaria **Previous treatment for malaria:** Not mentioned, either as an exclusion criteria or characteristic of included participants **Clinical setting:** Local clinic **Country:** Zimbabwe (Burma Valley, Mutarre District, Manicaland) **Malaria endemicity:** Mesoendemic **Malaria endemic species:** *P. falciparum*
Participants	**Sample size:** 123 for ICT Malaria Pf, 100 for ParaSight-F **Age:** Not mentioned, either as an exclusion criteria or characteristic of included participants **Sex:** Not mentioned, either as an exclusion criteria or characteristic of included participants **Co-morbidities and pregnancy:** Not mentioned, either as an exclusion criteria or characteristic of included participants **Parasite density of microscopy positive cases:** Not presented
Study design	Enrollment was prospective. The sampling method was not described. One RDT was tested.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy thick and thin blood films **Person(s) performing microscopy:** Microscopists **Microscopy setting:** Not stated **Number of high power fields examined before declaring negative:** Not stated. However, the alternative quality measure of viewing 300 white blood cells (WBCs) before declaring a slide negative was used. **Number of observer or repeats:** Two independent readers **Resolution of discrepancies between observers:** Not described
Index and comparator tests	**Commerical name of RDT:** ParaSight-F (Beckton Dickinson, Franklin Lakes, NJ, USA) ICT Malaria Pf (ICT Diagnostics, Brookvale, NSW, Australia) **Parasite(s) designed to detect:** *P. falciparum* **Designated Type:** Type 1 **Batch numbers:** Not stated **Transport and storage conditions:** Not described **Person(s) performing RDT:** Not stated **RDT setting:** Not stated
Follow-up	Not applicable
Notes	**Source of funding:** Not stated

Table of Methodological Quality

Item	Authors' judgement	Description

Murahwa 1999 (*Continued*)

Representative spectrum? All tests	Unclear	Participants were all people presenting at an outpatient clinic with clinical signs and symptoms of malaria, but the sampling method was not described
Acceptable reference standard? All tests	Unclear	Two independent microscopists viewed at least 300 WBCs. Unclear if this is equivalent to 100 high power fields.
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Yes	RDT tests results were coded and recorded separately for each test; two microscopists examined the slides blindly
Index test results blinded? All tests	Yes	RDT tests were performed and results recorded before microscopy was undertaken
Uninterpretable results reported? All tests	Yes	Six ICT Malaria tests and three ParaSight-F tests gave invalid results and were excluded from the analysis
Withdrawals explained? All tests	No	Unclear why only 100 of 123 participants received ParaSight-F

Mwanza 2005

Clinical features and settings	**Presenting signs and symptoms:** Fever **Previous treatment for malaria:** Not mentioned, either as an exclusion criteria or characteristic of included participants **Clinical setting:** Outpatient clinics **Country:** Zambia (copper belt, Ndola and Kitwe) **Malaria endemicity:** Not stated **Malaria endemic species:** Not stated
Participants	**Sample size:** 119 **Age:** Inclusion criteria: adults and children aged over 60 months **Sex:** Not reported, no mention of sex as inclusion or exclusion criteria **Co-morbidities and pregnancy:** Not reported, no mention of these conditions as inclusion or exclusion criteria

	Parasite density of microscopy positive cases: Not presented
Study design	Enrollment was prospective. The sampling method was not described. One RDT was tested.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy **Person(s) performing microscopy:** Not stated **Microscopy setting:** Not stated **Number of high power fields examined before declaring negative:** Not stated **Number of observer or repeats:** Not stated **Resolution of discrepancies between observers:** Not applicable
Index and comparator tests	**Commerical name of RDT:** Hexagon Malaria **Parasite(s) designed to detect:** *P. falciparum* **Designated Type:** Type 1 **Batch numbers:** Not stated **Transport and storage conditions:** Not described **Person(s) performing RDT:** Not stated **RDT setting:** Not stated
Follow-up	Not applicable
Notes	**Source of funding:** Not stated

Table of Methodological Quality

Item	**Authors' judgement**	**Description**
Representative spectrum? All tests	Unclear	Participants were all attending outpatient clinics with fever, however the sampling method was not described
Acceptable reference standard? All tests	Unclear	Microscopy process is not described
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Unclear	Blinding not described

Mwanza 2005 (*Continued*)

Index test results blinded? All tests	Unclear	Blinding not described
Uninterpretable results reported? All tests	Unclear	The number of participants originally enrolled in the study was not clearly stated, therefore it is unclear whether there were any exclusions due to invalid test results
Withdrawals explained? All tests	Unclear	The number of participants originally enrolled in the study was not clearly stated, therefore it is unclear whether there were any withdrawals

Nicastri 2009a

Clinical features and settings	**Presenting signs and symptoms:** Fever over 38 °C for less than 10 days **Previous treatment for malaria:** Participants with previous antimalarial treatment (timescale not stated) were excluded **Clinical setting:** Outpatient clinics at two peripheral hospitals **Country:** Tanzania (Pemba Island and Iringa) **Malaria endemicity:** Not stated **Malaria endemic species:** *P. falciparum*
Participants	**Sample size:** 336 **Age:** Inclusion criteria: adults and children aged over 12 months **Sex:** Not reported, no mention of sex as inclusion or exclusion criteria **Co-morbidities and pregnancy:** Excluded patients with signs of severe malaria, or with diagnoses of mental illness, measles, chickenpox, otitis, infected wounds or pneumonia **Parasite density of microscopy positive cases:** Not presented.
Study design	Enrolment was prospective. The sampling method was not described. One RDT was tested.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy thick and thin blood smears **Person(s) performing microscopy:** Laboratory technician trained and supported with blood slide reading **Microscopy setting:** Hospital laboratory **Number of high power fields examined before declaring negative:** 200 **Number of observer or repeats:** Not stated **Resolution of discrepancies between observers:** Not applicable
Index and comparator tests	**Commerical name of RDT:** ParaHIT-f (Span Diagnostics Ltd, Surat, India) **Parasite(s) designed to detect:** *P. falciparum* **Designated Type:** Type 1 **Batch numbers:** Not stated **Transport and storage conditions:** Not described **Person(s) performing RDT:** Laboratory technician

	RDT setting: Hospital laboratory
Follow-up	Not applicable
Notes	**Source of funding:** Part of the activities carried out by the Programme Aid 8282 in Tanzania, funded by the Italian Cooperation and Ministry of Foreign Affairs of Italy. The American Society of Tropical Medicine and Hygiene assisted with the publication expenses.

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	Unclear	All participants were attending an outpatient department with fever, but the sampling method was not described
Acceptable reference standard? All tests	Unclear	Skilled technicians viewed up to 200 high powered fields before declaring negative; however it is unclear how many observers or repeats were used
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Unclear	Blinding not described
Index test results blinded? All tests	Unclear	Blinding not described
Uninterpretable results reported? All tests	Yes	There do not appear to be any uninterpretable results, as the number of participants recruited into the study is clearly presented and corresponds with the number presented in the analysis
Withdrawals explained? All tests	Yes	There do not appear to be any withdrawals, as the number of participants recruited into the study is clearly presented and corresponds with the number presented in the analysis

Nicastri 2009b

Clinical features and settings	**Presenting signs and symptoms:** Fever over 38 °C for less than 10 days **Previous treatment for malaria:** Participants with previous antimalarial treatment (timescale not stated) were excluded **Clinical setting:** Outpatient clinics at two peripheral hospitals **Country:** Tanzania (Pemba Island and Iringa) **Malaria endemicity:** Not stated **Malaria endemic species:** *P. falciparum*
Participants	**Sample size:** 336 **Age:** Inclusion criteria: adults and children aged over 12 months **Sex:** Not reported, no mention of sex as inclusion or exclusion criteria **Co-morbidities and pregnancy:** Excluded patients with signs of severe malaria, or with diagnoses of mental illness, measles, chickenpox, otitis, infected wounds or pneumonia **Parasite density of microscopy positive cases:** Not clear
Study design	Enrollment was prospective. The sampling method was not described. One RDT was tested.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** PCR
Index and comparator tests	**Commerical name of RDT:** ParaHIT-f (Span Diagnostics Ltd, Surat, India) **Parasite(s) designed to detect:** *P. falciparum* **Designated Type:** Type 1 **Batch numbers:** Not stated **Transport and storage conditions:** Not described **Person(s) performing RDT:** Laboratory technician **RDT setting:** Hospital laboratory
Follow-up	Not applicable
Notes	**Source of funding:** Part of the activities carried out by the Programme Aid 8282 in Tanzania, funded by the Italian Cooperation and Ministry of Foreign Affairs of Italy. The American Society of Tropical Medicine and Hygiene assisted with the publication expenses

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	Unclear	All participants were attending an outpatient department with fever, but the sampling method was not described
Acceptable reference standard? All tests	Yes	Reference standard was PCR
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test

Nicastri 2009b (*Continued*)

Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Unclear	Blinding not described
Index test results blinded? All tests	Unclear	Blinding not described
Uninterpretable results reported? All tests	Unclear	There do not appear to be any uninterpretable results, as the number of participants recruited into the study is clearly presented and corresponds with the number presented in the analysis
Withdrawals explained? All tests	Yes	There do not appear to be any withdrawals, as the number of participants recruited into the study is clearly presented and corresponds with the number presented in the analysis

Nigussie 2008a

Clinical features and settings	**Presenting signs and symptoms:** Acutely febrile patients **Previous treatment for malaria:** No exclusions based on previous treatment; 220 participants were interviewed regarding previous antimalarial use and 24 of these (11%) reported antimalarial use in the previous month **Clinical setting:** Health centre outpatient departments **Country:** Ethiopia (Wondo-Genet) **Malaria endemicity:** Not stated **Malaria endemic species:** *P. falciparum* and *P. vivax*
Participants	**Sample size:** 460 enrolled, 452 received the test **Age:** All ages eligible. Actual age range 1 to 60 years. **Sex:** 242 males (52.6%), 218 females (47.4%) **Co-morbidities and pregnancy:** No exclusion criteria based on co-morbidities. No details of the frequency of these conditions in the participant population is presented. **Parasite density of microscopy positive cases:** Not presented
Study design	Enrollment was consecutive and prospective. Two RDTs were tested in the study, these are reported separately in this review.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy thick and thin blood films **Person(s) performing microscopy:** Technicians who were members of the research

	team, and independent readers at a central laboratory **Microscopy setting:** Health centres and Akilu Lemma Institute of Pathobiology parasitology laboratory **Number of high power fields examined before declaring negative:** 100 **Number of observer or repeats:** Two, one at the health centre and one at the central laboratory **Resolution of discrepancies between observers:** There were no discordant results
Index and comparator tests	**Commerical name of RDT:** Paracheck Pf (Orchid Biomedical Systems, Goa, India) **Parasite(s) designed to detect:** *P. falciparum* **Designated Type:** Type 1 **Batch numbers:** Not stated **Transport and storage conditions:** Not described **Person(s) performing RDT:** Two well experienced technicians who were part of the research team **RDT setting:** Health centres
Follow-up	Not applicable
Notes	**Source of funding:** Paracheck Pf kits were provided by the Federal Democratic Republic of Ethiopia Ministry of Health

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	Yes	Participants were a consecutive sample of people attending health centre outpatient departments with an acute fever
Acceptable reference standard? All tests	Yes	Two independent readers viewed at least 100 high power fields before declaring a slide negative. One reader was based at a central laboratory, and there were no discordant results between readers.
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Unclear	Blinding not described

Nigussie 2008a (*Continued*)

Index test results blinded? All tests	Unclear	Blinding not described
Uninterpretable results reported? All tests	Yes	Eight participants were excluded due either to incomplete information on either the Paracheck test or the malaria slide
Withdrawals explained? All tests	Yes	The number of participants enrolled in the study is clearly stated and corresponds to the number presented in the analysis minus the number reported to have invalid test results or incomplete data

Nigussie 2008b

Clinical features and settings	**Presenting signs and symptoms:** Acutely febrile patients **Previous treatment for malaria:** No exclusions based on previous treatment; 220 participants were interviewed regarding previous antimalarial use and 24 of these (11%) reported antimalarial use in the previous month **Clinical setting:** Health centre outpatient departments **Country:** Ethiopia (Wondo-Genet) **Malaria endemicity:** Not stated **Malaria endemic species:** *P. falciparum* and *P. vivax*
Participants	**Sample size:** 259 received RDT, although 460 were enrolled in the study **Age:** All ages eligible. Actual age range 1 to 60 years. **Sex:** Males and females eligible for the study, actual numbers who received Parascreen not presented **Co-morbidities and pregnancy:** No exclusions criteria based on co-morbidities. No details of the frequency of these conditions in the participant population is presented. **Parasite density of microscopy positive cases:** Not presented
Study design	Enrollment was consecutive and prospective. Two RDTs were tested in the study, these are reported separately in this review
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy thick and thin blood films **Person(s) performing microscopy:** Technicians who were members of the research team, and independent readers at a central laboratory **Microscopy setting:** Health centres and Akilu Lemma Institute of Pathobiology parasitology laboratory **Number of high power fields examined before declaring negative:** 100 **Number of observer or repeats:** Two, one at the health centre and one at the central laboratory **Resolution of discrepancies between observers:** There were no discordant results

Index and comparator tests	**Commerical name of RDT:** Parascreen Pan/Pf (Zephyr Biomedical, Verna, Goa, India) **Parasite(s) designed to detect:** *P. falciparum* or mixed infection, non-*falciparum* species only **Designated Type:** Type 3 **Batch numbers:** Not stated **Transport and storage conditions:** Not described **Person(s) performing RDT:** Two well experienced technicians who were part of the research team **RDT setting:** Health centres
Follow-up	Not applicable
Notes	**Source of funding:** The Global Fund to fight AIDS, TB and Malaria through the Federal Democratic Republic Ethiopian Ministry of Health

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	Unclear	Due to a shortage of test kits, only 259 of the 460 participants enrolled in the study received this RDT test, and it is not clear how these participants were selected
Acceptable reference standard? All tests	Yes	Two independent readers viewed at least 100 high power fields before declaring a slide negative. One reader was based at a central laboratory and there were no discordant results between readers.
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Unclear	Blinding not described
Index test results blinded? All tests	Unclear	Blinding not described
Uninterpretable results reported? All tests	Yes	Eight participants were excluded due either to incomplete information on either the Paracheck test or the malaria slide

Withdrawals explained? All tests	Yes	The number of participants enrolled in the study is clearly stated and corresponds to the number presented in the analysis minus the number reported to have invalid test results or incomplete data

Nwuba 2001

Clinical features and settings	**Presenting signs and symptoms:** Fever 38 °C or above, or other symptoms indicative of malaria **Previous treatment for malaria:** No exclusions based on previous treatment. Approximately 60% of participants had taken antimalarial drugs one day to three weeks prior to the hospital visit. **Clinical setting:** Paediatric outpatient clinic, University College Hospital **Country:** Nigeria, Ibadan **Malaria endemicity:** Not stated **Malaria endemic species:** Not stated
Participants	**Sample size:** 77 **Age:** Children only. Age range not stated. **Sex:** Both males and females eligible. Actual proportions of males and females in the participant population not stated. **Co-morbidities and pregnancy:** No exclusion criteria based on co-morbidities. No details of the frequency of these conditions in the participant population is presented. **Parasite density of microscopy positive cases:** Not presented
Study design	Enrollment was prospective. The sampling method was not described. One RDT was evaluated.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy thick and thin blood films **Person(s) performing microscopy:** Stated as "workers" **Microscopy setting:** Hospital laboratory **Number of high power fields examined before declaring negative:** 200 **Number of observer or repeats:** Two independent microscopists **Resolution of discrepancies between observers:** Not stated
Index and comparator tests	**Commerical name of RDT:** ICT Malaria Pf (ICT Diagnostics, Sydney, Australia) **Parasite(s) designed to detect:** *P. falciparum* **Designated Type:** Type 1 **Batch numbers:** Not stated **Transport and storage conditions:** Not described. **Person(s) performing RDT:** Not stated **RDT setting:** Paediatric outpatient clinic
Follow-up	Not applicable
Notes	**Source of funding:** Not stated

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	Unclear	The study included 77% of children presenting to an outpatient clinic during the study period with fever or other symptoms of malaria; the method of selection of these patients was not described
Acceptable reference standard? All tests	Yes	The independent microscopists viewed at least 200 high power fields before declaring a slide negative. Level of training of the "two workers" is not described, but microscopy was undertaken in a major hospital environment, and we therefore assumed experienced microscopists.
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Yes	Report stated that the microscopists had no knowledge of the RDT test results
Index test results blinded? All tests	Yes	The test was carried out prior to the microscopy.
Uninterpretable results reported? All tests	Unclear	The number of participants originally enrolled in the study was not clearly stated, therefore it is unclear whether there were any exclusions due to invalid test results
Withdrawals explained? All tests	Unclear	The number of participants originally enrolled in the study was not clearly stated, therefore it is unclear whether there were any withdrawals

Omar 1999

Clinical features and settings	**Presenting signs and symptoms:** Febrile or other commonly associated malaria symptoms **Previous treatment for malaria:** Not mentioned either as an exclusion criteria or characteristic of included participants **Clinical setting:** Outpatient clinic at a Primary Healthcare Centre **Country:** Saudi Arabia **Malaria endemicity:** Not stated **Malaria endemic species:** 90% *P. falciparum*
Participants	**Sample size:** 38 **Age:** Included participants aged 7 to 80 years **Sex:** Male:Female ratio 3:1 **Co-morbidities and pregnancy:** Not mentioned **Parasite density of microscopy positive cases:** Mean 7476 parasites per μl
Study design	Enrollment was prospective. The sampling method was not described. One RDT was evaluated
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy thick blood film **Person(s) performing microscopy:** Microscopist checked by consultant **Microscopy setting:** Parasitology laboratory **Number of high power fields examined before declaring negative:** Not stated **Number of observer or repeats:** Two observers but unclear whether they worked independently **Resolution of discrepancies between observers:** Not stated
Index and comparator tests	**Commerical name of RDT:** ParaSIght-F (Beckton Dickinson, Franklin Lakes, NJ, USA) **Parasite(s) designed to detect:** *P. falciparum* **Designated Type:** Type 1 **Batch numbers:** Not stated **Transport and storage conditions:** Not described. **Person(s) performing RDT:** Two investigators **RDT setting:** Not stated
Follow-up	Not applicable
Notes	**Source of funding:** Not stated

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	Unclear	Participants were attending outpatient clinics with fever or other symptoms of malaria, but the sampling method was not described

Omar 1999 (*Continued*)

Acceptable reference standard? All tests	Unclear	Unclear how many high power fields were examined before declaring a slide negative and unclear if the two observers worked independently
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Unclear	Blinding not described
Index test results blinded? All tests	Unclear	Blinding not described
Uninterpretable results reported? All tests	Unclear	The number of participants originally enrolled in the study was not clearly stated, therefore it is unclear whether there were any exclusions due to invalid test results
Withdrawals explained? All tests	Unclear	The number of participants originally enrolled in the study was not clearly stated, therefore it is unclear whether there were any withdrawals

Pandya 2001

Clinical features and settings	**Presenting signs and symptoms:** Fever **Previous treatment for malaria:** No exclusions based on previous treatment and no data presented on previous treatment **Clinical setting:** Regional Health and Family Welfare Office Malaria Clinic **Country:** India (Gujarat) **Malaria endemicity:** Not stated **Malaria endemic species:** *P. falciparum and P. vivax*
Participants	**Sample size:** 468 **Age:** 10 aged under 5 years, 458 aged 5 and older **Sex:** 298 males, 170 females **Co-morbidities and pregnancy:** No exclusions due to co-morbidities or pregnancy, and actual numbers of participants with these conditions not presented **Parasite density of microscopy positive cases:** Not presented

Pandya 2001 (*Continued*)

Study design	Enrollment appeared to be consecutive, but may have been based only on those for whom a blood slide had been taken (criteria for taking blood slide unclear). Enrollment was prospective. One RDT was evaluated.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy thick blood film **Person(s) performing microscopy:** Not stated **Microscopy setting:** Not stated **Number of high power fields examined before declaring negative:** Not stated **Number of observer or repeats:** Not stated **Resolution of discrepancies between observers:** Not applicable
Index and comparator tests	**Commerical name of RDT:** Paracheck-Pf (Orchid Biomedical Systems, Goa, India) **Parasite(s) designed to detect:** *P. falciparum* **Designated Type:** Type 1 **Batch numbers:** Not stated **Transport and storage conditions:** Not described. **Person(s) performing RDT:** Not stated **RDT setting:** Not stated
Follow-up	Not applicable
Notes	**Source of funding:** Not stated

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	Unclear	All participants were children attending a clinic with fever, but the sampling method was unclear
Acceptable reference standard? All tests	Unclear	No description of the microscopy process provided
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Unclear	Blinding not described
Index test results blinded? All tests	Unclear	Blinding not described

Pandya 2001 (*Continued*)

Uninterpretable results reported? All tests	No	One enrolled individual is missing from the results table. The reason for this is unclear.
Withdrawals explained? All tests	No	One enrolled individual is missing from the results table. The reason for this is unclear.

Pattanasin 2003

Clinical features and settings	**Presenting signs and symptoms:** Fever or history of fever and suspected diagnosis of uncomplicated malaria **Previous treatment for malaria:** No mention of previous treatment for malaria, either as an exclusion criteria or a characteristic of included participants **Clinical setting:** Not stated **Country:** Thailand (Mae Sod) **Malaria endemicity:** Not stated, peak transmission season **Malaria endemic species:** *P. falciparum and P. vivax*
Participants	**Sample size:** 271 **Age:** Children aged under 2 years were excluded. The study included participants aged two to 81 years; 71% were aged under 15 years. **Sex:** Male: female ratio was 1.7:1 **Co-morbidities and pregnancy:** Pregnant women were excluded **Parasite density of microscopy positive cases:** Not presented
Study design	Enrolment was prospective. The sampling method was not described. Two RDTs were evaluated, the vast majority of participants received both RDTs.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy thick and thin blood film **Person(s) performing microscopy:** Not stated **Microscopy setting:** Not stated **Number of high power fields examined before declaring negative:** Not stated **Number of observer or repeats:** Not stated **Resolution of discrepancies between observers:** Not applicable
Index and comparator tests	**Commerical name of RDT:** Paracheck-Pf (Orchid Biomedical Systems, Goa, India) OptiMAL-IT (DiaMed AG, Cressier, Switzerland) **Parasite(s) designed to detect:** Paracheck-Pf - *P. falciparum* OptiMAL-IT - *P. falciparum* or mixed infection, non-*falciparum* species only **Designated Type:** Paracheck-Pf - Type 1 OptiMAL-IT - Type 4 **Batch numbers:** Not stated **Transport and storage conditions:** Kept at room temperature and opened just before performing the test to avoid humidity **Person(s) performing RDT:** Not stated

	RDT setting: Not stated	
Follow-up	Not applicable	
Notes	**Source of funding:** Not stated	

Table of Methodological Quality

Item	**Authors' judgement**	**Description**
Representative spectrum? All tests	Unclear	All participants had a fever and suspected malaria, but the exact clinical setting and the sampling method were not described
Acceptable reference standard? All tests	Unclear	No details of the microscopy process given
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Unclear	Blinding not described
Index test results blinded? All tests	Yes	Test results were recorded without reference to the microscopy results
Uninterpretable results reported? All tests	Yes	Doubtful and invalid results were reported (4 of 271)
Withdrawals explained? All tests	Unclear	Almost all participants were reported to receive the same index and reference tests (271 participants in total: 266 received OptMAL, 269 received Paracheck-Pf); the numbers presented in the analysis correspond

Rakotonirina 2008

Clinical features and settings	**Presenting signs and symptoms:** Fever over 37.5 °C or history of fever in the previous 24 h **Previous treatment for malaria:** Participants with recent antimalarial use were not excluded from the study; 34% of participants declared antimalarial use **Clinical setting:** Two primary health centres **Country:** Madagascar (Tsiroanomandidy on the west foothill areas of the Highlands) **Malaria endemicity:** Low and predominantly seasonal **Malaria endemic species:** *P. falciparum* (80%) and *P. vivax*
Participants	**Sample size:** 313 **Age:** All age groups were eligible for inclusion; the actual age range of the included participants was 6 months to 79 years (median age 10 years) **Sex:** Male: Famale ratio was 1.2:1 **Co-morbidities and pregnancy:** Pregnant women were excluded, as were people with signs of severe or complicated malaria **Parasite density of microscopy positive cases:** Range 32 to 52,750 parasites per μl, mean 4104, Standard Deviation 7894
Study design	Enrolment was consecutive and prospective. Two RDTs were evaluated; all participants received both RDTs.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** PCR
Index and comparator tests	**Commerical name of RDT:** OptiMAL-IT (DiaMed AG, Cressier, Switzerland) PALUTOP **Parasite(s) designed to detect:** OptiMAL-IT - *P. falciparum* or mixed infection, non-*falciparum* species only PALUTOP - *P. falciparum, P.vivax* and other malaria types **Designated Type:** OptiMAL-IT - Type 4 PALUTOP - Type 6 **Batch numbers:** OptiMAL-IT - 46110.85.01 PALUTOP - 91014 **Transport and storage conditions:** Transported and maintained at the study sites (primary health centres) at room temperature and opened just before use to avoid humidity damage **Person(s) performing RDT:** Trained technician **RDT setting:** Primary health centres
Follow-up	Not applicable
Notes	**Source of funding:** Global Fund Project for Madagascar, Round 3

Table of Methodological Quality

Item	Authors' judgement	Description

Rakotonirina 2008 (*Continued*)

Representative spectrum? All tests	Yes	Participants were a consecutive sample of patients attending primary health centres with fever or history of fever in the previous 24 h
Acceptable reference standard? All tests	Yes	Reference standard was PCR
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Yes	Stated that the PCR operator was blind to the results of the other tests performed
Index test results blinded? All tests	Yes	Stated that the test readers were blind to the results of the other tests performed
Uninterpretable results reported? All tests	Yes	There were no test failures with either RDT
Withdrawals explained? All tests	Yes	The number of participants enrolled in the study is clearly stated and corresponds to the number presented in the analysis

Ratsimbasoa 2007

Clinical features and settings	**Presenting signs and symptoms:** Fever over 37.5 °C or history of fever in the previous 24 h, with typical malaria symptoms. Patients with signs of severe or complicated malaria were excluded. **Previous treatment for malaria:** Participants with recent antimalarial use were not excluded from the study; 17% of participants reported antimalarial use **Clinical setting:** Primary health centres **Country:** Madagascar. Rural areas of Mahasolo (western foothills areas of the highlands) and Saharevo (eastern foothills areas of the highlands). **Malaria endemicity:** Low and predominantly seasonal in both areas **Malaria endemic species:** Predominantly *P. falciparum;* some *P. vivax*
Participants	**Sample size:** 194 **Age:** All groups eligible for inclusion not stated; actual age range of the included participants was 1 to 79 years (mean age 15.2 years); 12.9% were under five years of age **Sex:** Male: female ratio was 0.98:1 **Co-morbidities and pregnancy:** Pregnant women were excluded, as were people with

	signs of severe or complicated malaria **Parasite density of microscopy positive cases:** Range 16 to 233,600 parasites per μl, mean 6564, Standard Deviation 26,553
Study design	Enrolment was prospective. The sampling method was not described. Two RDTs were evaluated, all participants received both RDTs.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy thick and thin blood films **Person(s) performing microscopy:** An experienced technician **Microscopy setting:** Not stated **Number of high power fields examined before declaring negative:** 200 **Number of observer or repeats:** One **Resolution of discrepancies between observers:** Not applicable
Index and comparator tests	**Commerical name of RDT:** CareStart Malaria Pf/Pan (Access Bio Inc., Monmouth Junction, NJ, USA) SD Malaria Antigen Bioline Pf/Pan (Standard Diagnostics, Suwon City, South Korea) OptiMAL-IT (DiaMed AG, Cressier, Switzerland) **Parasite(s) designed to detect:** *P. falciparum* or mixed infection, non-*falciparum* species only **Designated Type:** Type 4 **Batch numbers:** CareStart Malaria - J25IL, J35IL, J45IL, J55IL SD Malaria Antigen Bioline - T5001, T5002, T5003, T5004 OptiMAL-IT - 46110.73.01, 46110.74.01, 46110.75.01 **Transport and storage conditions:** Transported and maintained at the study sites (primary health centres) at room temperature and opened just before use to avoid humidity damage **Person(s) performing RDT:** A technician **RDT setting:** Not stated
Follow-up	Not applicable
Notes	**Source of funding:** Global Fund Project for Madagascar, Round 3. The manufacturers supplied the test kits.

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	Unclear	All participants were attending primary health centres with fever and symptoms of malaria, but the sampling method was not described
Acceptable reference standard? All tests	No	An expert technician viewed 200 high power fields before declaring a slide negative; however their findings were not veri-

Ratsimbasoa 2007 (*Continued*)

		fied by a second independent reader
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Yes	"Analyzed without reference to the RDT results"
Index test results blinded? All tests	Yes	The RDTs were undertaken before the microscopy
Uninterpretable results reported? All tests	Unclear	The number recruited into the study was clearly stated, and corresponded with the number presented in the analysis
Withdrawals explained? All tests	Yes	The number recruited into the study was clearly stated, and corresponded with the number presented in the analysis

Ratsimbasoa 2008

Clinical features and settings	**Presenting signs and symptoms:** Fever or fever in the previous 24 h with typical malaria symptoms **Previous treatment for malaria:** Participants with recent antimalarial use were not excluded from the study; 13% of participants declared antimalarial use **Clinical setting:** Primary Health Centre **Country:** Madagascar (Ampasimpotsy, Central Highlands) **Malaria endemicity:** Transmission is low and predominantly seasonal. This study was carried out in the low season. **Malaria endemic species:** *P. falciparum* (approximately 75%) and *P. vivax*
Participants	**Sample size:** 200 **Age:** Eligible age range not stated; actual age range of the included participants was 6 months to 73 years (40% under 5 years, 26.5% 5 to 15 years) **Sex:** Male:female ratio was 1.2:1 **Co-morbidities and pregnancy:** Pregnant women were excluded, as were people with signs of severe or complicated malaria **Parasite density of microscopy positive cases:** Range 16 to 285,00 parasites per μl, mean 16,757, Standard Deviation 42,631
Study design	Enrolment was prospective. The sampling method was not described. Two RDTs were evaluated, all participants received both RDTs.

Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** PCR
Index and comparator tests	**Commerical name of RDT:** SD Bioline Malaria Ag Pf (Standard Diagnostics Inc., Suwon City, South Korea) (excluded as required data could not be extracted) SD Bioline Malaria Ag Pf/Pan (Standard Diagnostics Inc., Suwon City, South Korea) **Parasite(s) designed to detect:** SD Bioline Malaria Ag Pf - *P. falciparum* SD Bioline Malaria Ag Pf/Pan - *P. falciparum* or mixed infection, non-*falciparum* species only **Designated Type:** SD Bioline Malaria Ag Pf - Type 1 SD Bioline Malaria Ag Pf/Pan - Type 3 **Batch numbers:** SD Bioline Malaria Ag Pf - 05FK50 SD Bioline Malaria Ag Pf/Pan - 05FK60 **Transport and storage conditions:** All tests were kept at room temperature and opened just before use to avoid humidity damage. **Person(s) performing RDT:** Not stated **RDT setting:** Not stated
Follow-up	Not applicable
Notes	**Source of funding:** Kozone, representing Standard Diagnostics Inc in Madagascar

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	Unclear	Participants were all attending a health centre with fever and typical symptoms of malaria, but the sampling method was not described,
Acceptable reference standard? All tests	Yes	The reference standard was PCR
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Yes	PCR was carried out by technicians blind to the results of RDT testing

Ratsimbasoa 2008 (*Continued*)

Index test results blinded? All tests	Yes	RDTs were undertaken before the results of PCR were known
Uninterpretable results reported? All tests	Yes	Uninterpretable results are reported and excluded from the analysis. There were 2 invalid results for Bioline Pf and 1 for Bioline Pf/Pan
Withdrawals explained? All tests	No	There was one participant missing from the analysis for Bioline Pf/Pan, with no explanation

Sayang 2009

Clinical features and settings	**Presenting signs and symptoms:** Fever or history of fever in the previous 24 h, and nurse's suspicion of malaria **Previous treatment for malaria:** Patients who reported taking antimalarial drugs in the previous two weeks were excluded **Clinical setting:** Primary health centre **Country:** Yoaunde, Cameroon **Malaria endemicity:** Reported to be high **Malaria endemic species:** *P. falciparum*
Participants	**Sample size:** 153 **Age:** Both adults and children were included; there is no indication of the proportion of adults and children in the sample **Sex:** Not mentioned either as an exclusion criteria or a characteristic of included participants **Co-morbidities and pregnancy:** Not mentioned either as an exclusion criteria or a characteristic of included participants **Parasite density of microscopy positive cases:** Range 40 to 125,000 parasites per μl. Geometric mean: age 0-2 = 2869; age 3-5 = 6440; age 6-10 = 1580; age over 11 = 1535
Study design	Enrollment was prospective. The sampling method was initially consecutive, from which a random sample of patients assigned to RDTs. One RDTs was evaluated.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy **Person(s) performing microscopy:** Not stated **Microscopy setting:** Laboratory not further described **Number of high power fields examined before declaring negative:** Not stated **Number of observer or repeats:** Not stated **Resolution of discrepancies between observers:** Not applicable
Index and comparator tests	**Commerical name of RDT:** Diaspot cassette device (Acumen Diagnostics Inc, USA) **Parasite(s) designed to detect:** *P. falciparum* **Designated Type:** Type 1 **Batch numbers:** Not stated

	Transport and storage conditions: Not described **Person(s) performing RDT:** Nurses trained in the use of the device **RDT setting:** Primary Health Centre
Follow-up	Not applicable
Notes	**Source of funding:** Supported by the Service de Cooperation et d'Action Culturelle of the French Embassy in Yaounde, European Union (READ-UP project, STREP, contract no. 018602) and the Centre de Formation et Recherche en Medicine et Sante Tropicale, Marseille, France

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	Yes	Participants were all attending health centre, had fever and a nurse suspected that they might have malaria. Enrolment into the main study was consecutive, and allocation to RDT study was random.
Acceptable reference standard? All tests	Unclear	No details given of number of high power fields viewed before declaring negative, or number of observers or repeats
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Yes	Microscopy undertaken at a different site to RDTs
Index test results blinded? All tests	Yes	RDTs undertaken before microscopy, and at a different site
Uninterpretable results reported? All tests	Unclear	The number of participants originally enrolled in the study was not clearly stated, therefore it is unclear whether there were any exclusions due to invalid test results
Withdrawals explained? All tests	Unclear	The number of participants originally enrolled in the study was not clearly stated, therefore it is unclear whether there were any withdrawals

Sharew 2009

Clinical features and settings	**Presenting signs and symptoms:** Febrile patients, clinically suspected for malaria **Previous treatment for malaria:** No exclusions based on previous treatment. Information on previous treatment collected, but actual data not provided. **Clinical setting:** Outpatient departments of two health centres **Country:** Ethiopia (Southern - Wondo Genet) **Malaria endemicity:** Takes place throughout the year **Malaria endemic species:** *P. falciparum* and *P. vivax*
Participants	**Sample size:** 668 **Age:** All age groups eligible. Actual age range 6 months to 75 years. **Sex:** 361 (54%) males, 307 (46%) females **Co-morbidities and pregnancy:** No exclusion criteria based on co-morbidities or pregnancy. No details of the frequency of these conditions in the participant population is presented. **Parasite density of microscopy positive cases:** Not presented
Study design	Enrollment was consecutive and prospective. Two different RDTs were evaluated, and each participant received both tests.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy thick and thin blood films **Person(s) performing microscopy:** Experienced malaria technicians **Microscopy setting:** Not stated, but in the Wondo Genet area **Number of high power fields examined before declaring negative:** 100 **Number of observer or repeats:** Two independent technicians, also checked by the team leader **Resolution of discrepancies between observers:** All discordant results between microscopy and RDTs were repeated
Index and comparator tests	**Commerical name of RDT:** Paracheck Pf (Orchid Biomedical Systems, Goa, India) CareStart Malaria Pf/Pv Combo test (Access Bio Inc., New Jersey, USA) **Parasite(s) designed to detect:** *P. falciparum* Paracheck Pf - *P. falciparum* CareStart Malaria Pf/Pv Combo test - *P. falciparum, P. vivax* or mixed infection **Designated Type:** Paracheck Pf - Type 1 CareStart Malaria Pf/Pv Combo test - Type 5 **Batch numbers:** Not stated **Transport and storage conditions:** As per the instructions of the manufacturer **Person(s) performing RDT:** Not stated **RDT setting:** Two health centres
Follow-up	Not applicable
Notes	**Source of funding:** School of Graduate Studies of the Addis Adaba University through the Graduate Programme in Tropical and Infectious Diseases, Aklilu Lemma Institute of Pathobiology and from the Federal Ministry of Health of Ethiopia. Federal Ministry of Health of Ethiopia and Access Bio Inc. donated the test kits.

Sharew 2009 (*Continued*)

Table of Methodological Quality		
Item	**Authors' judgement**	**Description**
Representative spectrum? All tests	Yes	Participants were a consecutive sample of febrile patients attending health centres with suspected malaria
Acceptable reference standard? All tests	Yes	Two experienced microscopists independently viewed 100 high power fields before declaring a slide negative
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Unclear	Not described
Index test results blinded? All tests	Yes	Strict blinding with the results available before microscopy reported
Uninterpretable results reported? All tests	Yes	If a test was uninterpretable then it was repeated
Withdrawals explained? All tests	Yes	The number of participants enrolled in the study was clearly stated and corresponds to the number included in the analysis; therefore there were no withdrawals

Sharma 1999

Clinical features and settings	**Presenting signs and symptoms:** Clinical symptoms of malaria **Previous treatment for malaria:** No exclusions based on previous treatment. Information on previous treatment collected, but actual data not provided except in the case of false positive results. **Clinical setting:** Malaria Clinics **Country:** Orissa, India **Malaria endemicity:** Not stated **Malaria endemic species:** Mainly *P. falciparum,* some *P. vivax*

Sharma 1999 (*Continued*)

Participants	**Sample size:** 125 **Age:** Not mentioned either as an inclusion criteria or characteristic of the included participants **Sex:** Not mentioned either as an inclusion criteria or characteristic of the included participants **Co-morbidities and pregnancy:** No exclusion criteria based on co-morbidities or pregnancy. No details of the frequency of these conditions in the participant population is presented. **Parasite density of microscopy positive cases:** Range 40 to 36,000 parasites per μl
Study design	Enrollment was prospective. Random sampling was used, but exact method used to obtain a random sample was not stated. One RDT was evaluated.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy thick and thin blood films **Person(s) performing microscopy:** Not stated **Microscopy setting:** Not stated **Number of high power fields examined before declaring negative:** Not stated **Number of observer or repeats:** Results discordant between microscopy and RDT were re-examined for confirmation of the results **Resolution of discrepancies between observers:** Not described
Index and comparator tests	**Commerical name of RDT:** ICT Malaria Pf (ICT Diagnostics, Sydney, Australia) **Parasite(s) designed to detect:** *P. falciparum* **Designated Type:** Type 1 **Batch numbers:** Not stated **Transport and storage conditions:** Not described **Person(s) performing RDT:** Various clinic staff **RDT setting:** Malaria clinics
Follow-up	Not applicable
Notes	**Source of funding:** Not stated

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	Yes	Participants were a random sample of people attending a clinic with clinical symptoms of malaria
Acceptable reference standard? All tests	Unclear	Discordant results between RDTs and microscopy were re-examined; however it is unclear how many high power fields were viewed before declaring a slide negative

Sharma 1999 (*Continued*)

Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Yes	"Evaluation was double blind"
Index test results blinded? All tests	Yes	"Evaluation was double blind"
Uninterpretable results reported? All tests	Yes	There were five uninterpretable test results; these were excluded from the analysis
Withdrawals explained? All tests	Yes	The numbers enrolled in the study and the numbers with data presented for them correspond, with the exception of the five excluded from the analysis due to uninterpretable test results

Singh 1997 (a)

Clinical features and settings	**Presenting signs and symptoms:** Fever **Previous treatment for malaria:** No exclusions based on previous treatment. Data was collected on previous treatment, but was only presented in the case of false positive results. **Clinical setting:** Field workers in villages **Country:** India (Maldla District, Central India) **Malaria endemicity:** Seasonal **Malaria endemic species:** *P. falciparum* and *P. vivax,* but during the seasons the study was undertaken, mainly *P. falciparum*
Participants	**Sample size:** 353 **Age:** Not mentioned either as an inclusion criteria or characteristic of the included participants **Sex:** Not mentioned either as an inclusion criteria or characteristic of the included participants **Co-morbidities and pregnancy:** Not mentioned either as an exclusion criteria or characteristic of the included participants **Parasite density of microscopy positive cases:** Range 60 to 7,000 parasites per μl
Study design	Enrollment was consecutive and prospective. One RDT was evaluated.

Singh 1997 (a) (*Continued*)

Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy thick blood films **Person(s) performing microscopy:** Microscopist at central research centre **Microscopy setting:** Blood films were prepared in villages and examined by at the Malaria Research Centre in Delhi **Number of high power fields examined before declaring negative:** Not stated; 250 WBCs were examined before classifying a slide as negative. All negative slides were re-examined by counting up to 2500 WBCs. **Number of observer or repeats:** One, although intimally negative slides were re-examined **Resolution of discrepancies between observers:** Not applicable
Index and comparator tests	**Commerical name of RDT:** ICT Malaria Pf (ICT Diagnostics, Sydney, Australia) **Parasite(s) designed to detect:** *P. falciparum* **Designated Type:** Type 1 **Batch numbers:** Not stated **Transport and storage conditions:** Not described **Person(s) performing RDT:** Field workers **RDT setting:** Villages (actual setting not well described)
Follow-up	Not applicable
Notes	**Source of funding:** Not stated

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	Unclear	It is unclear as to whether passive or active case-finding was used, as field workers went into villages
Acceptable reference standard? All tests	No	Only one observer was used, and the number of high power fields viewed before declaring a slide negative was not stated
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Yes	"without reference to the result of the ICT"

Singh 1997 (a) (*Continued*)

Index test results blinded? All tests	Yes	Index test results were available before the reference test results
Uninterpretable results reported? All tests	Unclear	The number of participants originally enrolled in the study was clearly stated and the number presented in the analysis corresponded; therefore there were no exclusions due to uninterpretable test results
Withdrawals explained? All tests	Yes	The number of participants originally enrolled in the study was clearly stated and the number presented in the analysis corresponded; therefore there were no withdrawals

Singh 1997 (b)

Clinical features and settings	**Presenting signs and symptoms:** Fever **Previous treatment for malaria:** No exclusions based on previous treatment. No data presented on numbers who had previously been treated, although this information was recorded for each participant. **Clinical setting:** Malaria clinic established within a Primary Health Centre specifically for the study **Country:** India (Maldla District, Central India) **Malaria endemicity:** Seasonal **Malaria endemic species:** *P. falciparum* and *P. vivax,* but during the seasons the study was undertaken, mainly *P. falciparum*
Participants	**Sample size:** 1231 **Age:** Not mentioned either as an inclusion criteria or characteristic of the included participants **Sex:** Not mentioned either as an inclusion criteria or characteristic of the included participants **Co-morbidities and pregnancy:** Not mentioned either as exclusion criteria or as characteristics of the included participants **Parasite density of microscopy positive cases:** Not presented
Study design	Enrollment was consecutive and was prospective. One RDT was evaluated.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy thick blood films **Person(s) performing microscopy:** Microscopist **Microscopy setting:** Not stated **Number of high power fields examined before declaring negative:** Not stated. 1000 white blood cells were initially counted before declaring negative, with a repeat looking at 4000 WBCs if initially negative **Number of observer or repeats:** Negative slides were checked by another observer. **Resolution of discrepancies between observers:** Not described.

Singh 1997 (b) (*Continued*)

Index and comparator tests	**Commerical name of RDT:** ParaSight-F (Beckton Dickinson, Franklin Lakes, NJ, US) **Parasite(s) designed to detect:** *P. falciparum* **Designated Type:** Type 1 **Batch numbers:** Not stated **Transport and storage conditions:** Not described **Person(s) performing RDT:** Two independent technicians **RDT setting:** Malaria clinic
Follow-up	Not applicable
Notes	**Source of funding:** WHO Special Program for Research and Training in Tropical Diseases

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	Yes	Participants were a consecutive sample of people attending a malaria clinic with fever
Acceptable reference standard? All tests	No	Only one observer was used for slides initially found positive. Unclear whether 100 high power fields viewed before declaring negative, although an alternative criteria of 4000 WBCs was used
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Unclear	Blinding not described
Index test results blinded? All tests	Unclear	Blinding not described
Uninterpretable results reported? All tests	Unclear	The number of participants originally enrolled in the study was clearly stated and the number presented in the analysis corresponded; therefore there were no exclusions due to uninterpretable test results

Singh 1997 (b) (*Continued*)

Withdrawals explained? All tests	Yes	The number of participants originally enrolled in the study was clearly stated and the number presented in the analysis corresponded; therefore there were no withdrawals

Singh 2000 (a)

Clinical features and settings	**Presenting signs and symptoms:** Clinically suspected malaria, including fever **Previous treatment for malaria:** No exclusions based on previous treatment, and no data reported; however the study was undertaken in a remote area with little access to malaria treatment **Clinical setting:** Mobile field clinic and laboratory **Country:** India **Malaria endemicity:** epidemic-prone forest villages in Madhya Pradesh, central India **Malaria endemic species:** *P. falciparum* (83.7% of positives) and *P. vivax*
Participants	**Sample size:** 526 **Age:** All age groups eligible. Adults and children included, but actual age profile of participant population not presented. **Sex:** Both males and females eligible. Actual proportions of males and females in the participant population not stated. **Co-morbidities and pregnancy:** No exclusion criteria based on co-morbidities or pregnancy. No details of the frequency of these conditions in the participant population is presented. **Parasite density of microscopy positive cases:** Not presented
Study design	Enrollment was consecutive and prospective. One RDT was evaluated.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy thick and thin blood films **Person(s) performing microscopy:** Microscopists **Microscopy setting:** Mobile laboratory **Number of high power fields examined before declaring negative:** Not stated **Number of observer or repeats:** One, but negative blood smears were re-examined if the corresponding RDT result was positive or if *P. vivax* was diagnosed **Resolution of discrepancies between observers:** Not applicable
Index and comparator tests	**Commerical name of RDT:** Determine malaria P.f. (Abbott Laboratories, Tokyo, Japan) **Parasite(s) designed to detect:** *P. falciparum* **Designated type:** Type 1 **Batch numbers:** Not stated **Transport and storage conditions:** Not described **Person(s) performing RDT:** Members of the field team of the malaria research centre undertook the test after receiving one hour of training. A technician interpreted all the test results. **RDT setting:** Mobile laboratory

Singh 2000 (a) (*Continued*)

Follow-up	Not applicable
Notes	**Source of funding:** Not stated. DP Medical Diagnostics (Ahmedaba Gujarat) supplied the RDTs free of charge.

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	Yes	Participants were a consecutive sample of people with clinically suspected malaria, presenting at an ambulatory clinic in an endemic area
Acceptable reference standard? All tests	No	Microscopy was undertaken by a single microscopist. There was no report of the number of high power fields viewed before declaring a slide negative.
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Yes	Study report states that microscopists were blinded to the RDT results
Index test results blinded? All tests	Yes	All RDTs were undertaken and the results known before microscopy
Uninterpretable results reported? All tests	Unclear	The number of participants originally enrolled in the study was clearly stated and the number presented in the analysis corresponded; therefore there were no exclusions due to uninterpretable test results
Withdrawals explained? All tests	Yes	The number of participants originally enrolled in the study was clearly stated and the number presented in the analysis corresponded; therefore there were no withdrawals

Singh 2000 (c)

Clinical features and settings	**Presenting signs and symptoms:** Fever suspected to be malaria **Previous treatment for malaria:** There were no exclusions based on previous treatment, and no information presented; this was an outbreak in a rural area **Clinical setting:** Mobile field laboratory **Country:** India (forest villages in Chhindwara, central India) **Malaria endemicity:** Outbreak situation **Malaria endemic species:** *P. falciparum* and *P. vivax*
Participants	**Sample size:** 344 **Age:** All age groups eligible. Actual age range 6 months to 65 years. **Sex:** Both males and females eligible. Actual proportions of males and females in the participant population not stated. **Co-morbidities and pregnancy:** No exclusion criteria based on co-morbidities or pregnancy. No details of the frequency of these conditions in the participant population is presented. **Parasite density of microscopy positive cases:** Not presented
Study design	Enrollment was consecutive and prospective. One RDT was evaluated.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy thick blood film **Person(s) performing microscopy:** Experienced microscopist for all slides; expert microscopist for re-examined slides **Microscopy setting:** Mobile field laboratory for all slides; Malaria Research Centre at Jabalur for re-examined slides **Number of high power fields examined before declaring negative:** Not stated. However, 200 WBCs were counted as an alternative indicator; or 500 WBCs for slides that were re-examined. **Number of observer or repeats:** One, but negative blood smears were re-examined if the patient was having severe symptoms, the corresponding RDT result was positive, or if *P. vivax* was diagnosed **Resolution of discrepancies between observers:** Not described, most likely accepted the findings of second microscopist
Index and comparator tests	**Commerical name of RDT:** ICT Malaria Pf/Pv (AMRAD, Australia) **Parasite(s) designed to detect:** *P. falciparum* or mixed infection, non-*falciparum* species only **Designated type:** Type 2 **Batch numbers:** Not stated **Transport and storage conditions:** Not described **Person(s) performing RDT:** Field laboratory assistants **RDT setting:** Mobile field laboratory
Follow-up	Not applicable
Notes	**Source of funding:** Becton Dickinson provided financial support and supplied the RDTs free of charge

Table of Methodological Quality

Singh 2000 (c) (*Continued*)

Item	Authors' judgement	Description
Representative spectrum? All tests	Yes	All participants were attending an ambulatory setting with fever suspected to be malaria, and enrolment was consecutive
Acceptable reference standard? All tests	No	Microscopy was undertaken by one microscopist only; and the number of high power fields viewed was unclear (200 WBCs)
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Yes	"Blood films were examined...without reference to the results of ICT"
Index test results blinded? All tests	Yes	"All specimens were tested...who were blinded to the results of the blood smear tests"
Uninterpretable results reported? All tests	Unclear	The number of participants originally enrolled in the study was clearly stated and the number presented in the analysis corresponded; therefore there were no exclusions due to uninterpretable test results
Withdrawals explained? All tests	Yes	The number of participants originally enrolled in the study was clearly stated and the number presented in the analysis corresponded; therefore there were no withdrawals

Singh 2003a

Clinical features and settings	**Presenting signs and symptoms:** Fever or history of fever **Previous treatment for malaria:** No explicit exclusions based on previous treatment, and no data reported **Clinical setting:** Hospital malaria clinic **Country:** India, Jabalpur **Malaria endemicity:** Not stated **Malaria endemic species:** *P. falciparum* and *P. vivax* in roughly equal proportions
Participants	**Sample size:** 80 **Age:** All age groups eligible. Adults and children included; mean age 27.7 (SD 16.42) for males and 29 (SD 12.8) for females **Sex:** Both males and females eligible; included 28 males and 18 females **Co-morbidities and pregnancy:** No explicit exclusion criteria based on co-morbidities or pregnancy. No details of the frequency of these conditions in the participant population is presented. **Parasite density of microscopy positive cases:** Range 40 to 370,574 parasites per μl for *P. falciparum* and 318 to 9970 for *P. vivax*
Study design	Enrollment was prospective. The sampling method was not described. Only one RDT was evaluated.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy thick blood films **Person(s) performing microscopy:** Not stated **Microscopy setting:** Hospital laboratory **Number of high power fields examined before declaring negative:** Not stated **Number of observer or repeats:** If the results of the OptiMAL conflicted with that of microscopy for any sample, the blood smear was re-examined by a different technician **Resolution of discrepancies between observers:** If the re-examination of discordant results gave a different result to the first examination, the second result was confirmed by yet another technician
Index and comparator tests	**Commerical name of RDT:** OptiMAL **Parasite(s) designed to detect:** *P. falciparum* or mixed infection, non-*falciparum* species only **Designated type:** Type 4 **Batch numbers:** Not stated **Transport and storage conditions:** Not described **Person(s) performing RDT:** A technician **RDT setting:** Hospital clinic or laboratory
Follow-up	Not applicable
Notes	**Source of funding:** Not stated.

Table of Methodological Quality

Item	Authors' judgement	Description

Singh 2003a (*Continued*)

Representative spectrum? All tests	Unclear	Participants were all attending a clinic with fever or history of fever, but the sampling method was not described
Acceptable reference standard? All tests	Unclear	Discordant results between RDT and microscopy were re-examined; however the number of high power fields viewed before declaring a sample negative was not stated
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Unclear	Blinding not described
Index test results blinded? All tests	Yes	Technicans were blinded to the results of the blood smear examination
Uninterpretable results reported? All tests	Unclear	The number of participants originally enrolled in the study was clearly stated and the number presented in the analysis corresponded; therefore there were no exclusions due to uninterpretable test results
Withdrawals explained? All tests	Yes	The number of participants originally enrolled in the study was clearly stated and the number presented in the analysis corresponded; therefore there were no withdrawals

Singh 2003b

Clinical features and settings	**Presenting signs and symptoms:** Fever and chills of several days' duration **Previous treatment for malaria:** No explicit exclusions based on previous treatment, and no data reported **Clinical setting:** Field clinics **Country:** India, villages in the Jabalpur district **Malaria endemicity:** Not stated **Malaria endemic species:** *P. falciparum* and *P. vivax* in roughly equal proportions
Participants	**Sample size:** 75 **Age:** All age groups eligible. Adults and children included; mean age 20.4 (SD 17.00)

Singh 2003b (*Continued*)

	for males and 25.9 (SD 17.9) for females **Sex:** Both males and females eligible; included 25 males and 32 females **Co-morbidities and pregnancy:** No explicit exclusion criteria based on co-morbidities or pregnancy. No details of the frequency of these conditions in the participant population is presented. **Parasite density of microscopy positive cases:** Range 100 to 90,000 parasites per μl for *P. falciparum*, 835 to 4320 for *P. vivax*
Study design	Enrollment was prospective. The sampling method was not described. One RDT was evaluated.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy thick blood films **Person(s) performing microscopy:** Not stated **Microscopy setting:** Not stated **Number of high power fields examined before declaring negative:** Not stated **Number of observer or repeats:** If the results of the OptiMAL conflicted with that of microscopy for any sample, the blood smear was re-examined by a different technician **Resolution of discrepancies between observers:** If the re-examination of discordant results gave a different result to the first examination, the second result was confirmed by yet another technician
Index and comparator tests	**Commerical name of RDT:** OptiMAL (DiaMed AG, Cressier, Switzerland) **Parasite(s) designed to detect:** *P. falciparum* or mixed infection, non-*falciparum* species only **Designated type:** Type 4 **Batch numbers:** Not stated **Transport and storage conditions:** Not described **Person(s) performing RDT:** Not stated **RDT setting:** Not stated
Follow-up	Not applicable
Notes	**Source of funding:** Not stated.

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	Unclear	All participants were attending a field clinic with fever and chills of several days' duration, but the sampling method was not described
Acceptable reference standard? All tests	Unclear	Discordant results between RDT and microscopy were re-examined; however the number of high power fields viewed before declaring a sample negative was not stated

Singh 2003b (*Continued*)

Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Unclear	Blinding not described
Index test results blinded? All tests	Unclear	Blinding not described
Uninterpretable results reported? All tests	Unclear	The number of participants originally enrolled in the study was clearly stated and the number presented in the analysis corresponded; therefore there were no exclusions due to uninterpretable test results
Withdrawals explained? All tests	Yes	The number of participants originally enrolled in the study was clearly stated and the number presented in the analysis corresponded; therefore there were no withdrawals

Stephens 1999

Clinical features and settings	**Presenting signs and symptoms:** Unclear; participants were selected by triage from people presenting themselves at a hospital **Previous treatment for malaria:** No exclusions based on previous treatment; data presented on previous treatment only covers false positive cases **Clinical setting:** Hospital outpatient clinic **Country:** Thailand (North West - Mae Hong Son) **Malaria endemicity:** Perennial with seasonal peaks **Malaria endemic species:** *P. falciparum* and *P. vivax*
Participants	**Sample size:** 301 enrolled, 296 received RDT **Age:** All age groups eligible. Actual age range from less than one month to 81 years **Sex:** Male: female ratio 6:4 **Co-morbidities and pregnancy:** No explicit exclusion criteria based on co-morbidities or pregnancy. No details of the frequency of these conditions in the participant population is presented. **Parasite density of microscopy positive cases:** Not presented
Study design	Enrollment was prospective. The sampling method was not described. One RDT was evaluated.

Stephens 1999 (*Continued*)

Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy thick and thin blood films **Person(s) performing microscopy:** Microscopists **Microscopy setting:** Hospital laboratory **Number of high power fields examined before declaring negative:** Not stated **Number of observer or repeats:** Two; one viewed the thick film and another viewed the thin film. The two microscopists worked independently and their findings compared at the end of the study. **Resolution of discrepancies between observers:** Not described
Index and comparator tests	**Commerical name of RDT:** ParaSight-F (Becton Dickinson Tropical Disease Diagnostics, Sparks, MD, US) **Parasite(s) designed to detect:** *P. falciparum* **Designated type:** Type 1 **Batch numbers:** Not stated **Transport and storage conditions:** Not described **Person(s) performing RDT:** Not stated **RDT setting:** Hospital clinic or laboratory
Follow-up	Not applicable
Notes	**Source of funding:** Supported by Dr Surang Tanpridist, Director, Malaria Division, Ministry for Public Health, Nonthaburi, and Dr Somsak Prajakwongse, Director, Malaria Region 2, Chiang Mai, Thailand, and the DFID-funded Malaria Work Programme of the Liverpool School of Tropical Medicine

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	Unclear	The presenting symptoms and sampling methods were unclear
Acceptable reference standard? All tests	Unclear	No details of the number of high power fields viewed before declaring a slide negative, and no information on how the findings of the two microscopists were compared
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard

Stephens 1999 (*Continued*)

Reference standard results blinded? All tests	Unclear	Blinding not described
Index test results blinded? All tests	Unclear	Blinding not described
Uninterpretable results reported? All tests	Unclear	The number of participants originally enrolled in the study was clearly stated and the number presented in the analysis corresponded; therefore there were no exclusions due to uninterpretable test results
Withdrawals explained? All tests	Yes	Five of the participants originally enrolled did not received RDTs. With the exception of these five, the number of participants originally enrolled in the study was clearly stated and the number presented in the analysis corresponded.

Stow 1999

Clinical features and settings	**Presenting signs and symptoms:** Symptoms suggestive of malaria **Previous treatment for malaria:** Not mentioned **Clinical setting:** Hospital outpatient department **Country:** Kenya **Malaria endemicity:** Catchment area varied from holoendemic to seasonally endemic **Malaria endemic species:** *P. falciparum*
Participants	**Sample size:** 164 **Age:** Not mentioned either as an inclusion criteria or characteristic of included participants **Sex:** Males and females included **Co-morbidities and pregnancy:** Not reported, no mention of these conditions as inclusion or exclusion criteria **Parasite density of microscopy positive cases:** Not presented
Study design	Enrollment was prospective. The sampling method was not described. One RDT was evaluated.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy thick and thin blood films **Person(s) performing microscopy:** Expert microscopist **Microscopy setting:** Westmead Hospital, Sydney, Australia **Number of high power fields examined before declaring negative:** Not stated (examined for ten minutes) **Number of observer or repeats:** One **Resolution of discrepancies between observers:** Not applicable

Index and comparator tests	**Commerical name of RDT:** ICT Malaria Pf (ICT Diagnostics, Sydney, Australia) **Parasite(s) designed to detect:** *P. falciparum* **Designated type:** Type 1 **Batch numbers:** Not stated **Transport and storage conditions:** Not described **Person(s) performing RDT:** Not stated **RDT setting:** Hospital outpatient department
Follow-up	Not applicable
Notes	**Source of funding:** Not stated.

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	Unclear	All participants had symptoms suggestive of malaria, but the sampling method was not described
Acceptable reference standard? All tests	No	Only one microscopist was used, and the number of high power fields viewed before declaring negative was not specified (search time 10 minutes)
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Yes	Report stated that microscopists were blind to the results of the ICT test
Index test results blinded? All tests	Yes	The RDT was always performed and recorded before microscopy
Uninterpretable results reported? All tests	Unclear	The number of participants originally enrolled in the study was clearly stated and the number presented in the analysis corresponded; therefore there were no exclusions due to uninterpretable test results
Withdrawals explained? All tests	Yes	The number of participants originally enrolled in the study was clearly stated and the number presented in the analysis cor-

		responded; therefore there were no withdrawals

Tagbo 2007

Clinical features and settings	**Presenting signs and symptoms:** History of fever and body temperature 37.5 °C or higher **Previous treatment for malaria:** No exclusions based on previous antimalarial use, and no data presented on the numbers that previously used antimalarials **Clinical setting:** Outpatient department of all small private hospital for children **Country:** Nigeria **Malaria endemicity:** Holoendemic **Malaria endemic species:** *P. falciparum*
Participants	**Sample size:** 89 **Age:** Children only, mean age 3.6 years, range 2 weeks to 14 years **Sex:** 50 males and 39 females **Co-morbidities and pregnancy:** No exclusion criteria based on co-morbidities or pregnancy; 83 of the 89 included participants had a clinical diagnosis of malaria, the remaining 6 had other infections diagnosed clinically. Of the 83 with diagnosed malaria, 29 had acute respiratory infection, 4 had gastroenteritis and 4 had otitis media. **Parasite density of microscopy positive cases:** Mean 9058 parasites per μl
Study design	Enrollment was consecutive and prospective. One RDT was tested.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy thick and thin blood smears **Person(s) performing microscopy:** Certified medical laboratory scientists **Microscopy setting:** Nigeria Institute for Medical Research at Lagos **Number of high power fields examined before declaring negative:** at least 100 **Number of observer or repeats:** One **Resolution of discrepancies between observers:** Not applicable
Index and comparator tests	**Commerical name of RDT:** Paracheck Pf (Orchid Biomedical Systems, Goa, India) **Parasite(s) designed to detect:** *P. falciparum* **Designated Type:** Type 1 **Batch numbers:** 32037E **Transport and storage conditions:** Stored at room temperatures within the range of 4 °C and 30 °C recommended by the manufacturers **Person(s) performing RDT:** The study authors **RDT setting:** Outpatient clinic
Follow-up	Not applicable
Notes	**Source of funding:** Not stated

Table of Methodological Quality

Tagbo 2007 (*Continued*)

Item	Authors' judgement	Description
Representative spectrum? All tests	Yes	Participants were a consecutive sample of children with fever attending an outpatients clinic
Acceptable reference standard? All tests	No	Certified microscopists viewed at least 100 high power fields before declaring a slide negative, however their results were not verified by a second independent reader
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Yes	Reports that the laboratory was blinded to the results of the RDT
Index test results blinded? All tests	Yes	RDT was undertaken before the microscopy reference standard
Uninterpretable results reported? All tests	Unclear	The number of participants originally enrolled in the study was clearly stated and the number presented in the analysis corresponded; therefore there were no exclusions due to uninterpretable test results
Withdrawals explained? All tests	Yes	The number of participants originally enrolled in the study was clearly stated and the number presented in the analysis corresponded; therefore there were no withdrawals

Tjitra 1999

Clinical features and settings	**Presenting signs and symptoms:** Symptomatic with a presumptive clinical diagnosis of malaria: fever or history of fever in the last 24 h and no other obvious cause of fever **Previous treatment for malaria:** Prior use of antimalarials was not an exclusion criteria. Approximately half of the participants reported use of antimalarials within the previous 4 weeks. **Clinical setting:** Primary health centre **Country:** Indonesia (Laratama sub district, West Sumba, East Nusa Tenggara Province, Eastern Indonesia) **Malaria endemicity:** Infection rate in children 0 to 9 years of 5.1% **Malaria endemic species:** *P. falciparum* and *P. vivax*
Participants	**Sample size:** 560 **Age:** All ages eligible. Actual age range of the participants 0 to 80 years. **Sex:** Males and females eligible; 289 males and 271 females included **Co-morbidities:** Not mentioned either as an exclusion criteria or a characteristic of the included participants **Parasite density of microscopy positive cases:** *P. vivax* mean 7157 parasites per μl
Study design	Enrollment was prospective. The sampling method was not described. One RDT was tested.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy thick and thin blood smears **Person(s) performing microscopy:** Expert microscopists with over 20 years experience each **Microscopy setting:** One local (exact setting not stated); cross-checking was done in Darwin, Australia **Number of high power fields examined before declaring negative: A**t least 100 for all slides, at least 200 for those cross-checked **Number of observer or repeats:** One observer for the majority of slides; discordant results between microscopy and RDT and 20% of slides with concordant results were cross-checked by a second microscopist, blind to the results of first microscopy and RDT **Resolution of discrepancies between observers:** Not described
Index and comparator tests	**Commerical name of RDT:** ICT Malaria Pf/Pv **Parasite(s) designed to detect:** *P. falciparum* or mixed infection, non-*falciparum* species only **Designated Type:** Type 2 **Batch numbers:** 100088 for the first 393 tests, and 041388 for the remaining 167 tests **Transport and storage conditions:** Not described **Person(s) performing RDT:** Performed by trained health workers and read by a study physician blinded to the microscopy results **RDT setting:** Primary health centre
Follow-up	Not applicable
Notes	**Source of funding:** Financial assistance received from the Northern Territory Government 50th Anniversary of Indonesian Independence Malaria-Tuberculosis Research Fellowships. ICT Pf/Pv kits and some logistical costs were supported by AMRAD-ICT

Tjitra 1999 (*Continued*)

	Sydney, New South Wales, Australia.

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	Unclear	Participants were all attending a primary health care centre with fever and symptoms of malaria, but the sampling method was not described
Acceptable reference standard? All tests	Yes	All slides were read by an experienced microscopist viewing at least 100 high power fields, and results discordant with RDT were re-examined by another, independent microscopist
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Yes	"The microscopist was unaware of the immunochromatographic test result"
Index test results blinded? All tests	Yes	"The results were read by a study physician who was blinded to the microscopy results"
Uninterpretable results reported? All tests	Unclear	The number of participants enrolled in the study was clearly stated and corresponded to the number presented in the analysis; therefore there were no exclusions due to uninterpretable test results
Withdrawals explained? All tests	Yes	The number of participants enrolled in the study was clearly stated and corresponded to the number included in the analysis; therefore there were no withdrawals

Valecha 2003

Clinical features and settings	**Presenting signs and symptoms:** Fever or history of fever **Previous treatment for malaria:** Not mentioned, either as an exclusion criteria or a characteristic of included participants **Clinical setting:** Malaria clinics and village health workers **Country:** India (Delhi, Nadiad, Jabalpur and Sonapur) **Malaria endemicity:** Four sites of different endemicities **Malaria endemic species:** *P. falciparum* and *P. vivax*
Participants	**Sample size:** 699 **Age:** All ages eligible; age range of included participants 1 to 75 years (mean 22.8) **Sex:** Included 395 males and 304 females **Co-morbidities:** Not mentioned, either as an exclusion criteria or a characteristic of included participants **Parasite density of microscopy positive cases:** *P. vivax* range 40 to 44,000 parasites per μl, median 1020; *P. falciparu*m range 120 to 68,480 parasites per μl, median 2000
Study design	Enrollment was prospective. The sampling method was not described. One RDT was tested.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy **Person(s) performing microscopy:** Microscopist **Microscopy setting:** Not stated **Number of high power fields examined before declaring negative:** 100 **Number of observer or repeats:** One for most slides. All results discordant with RDT results and 20% of concordant results were cross-checked. Negative slides which tested positive by kit were re-examined by counting up to 2000 WBCs. **Resolution of discrepancies between observers:** In the case of initially negative slides looked at in more detail because of discordant results, the second reading was taken as true
Index and comparator tests	**Commerical name of RDT:** OptiMAL (DiaMed AG, Cressier, Switzerland) **Parasite(s) designed to detect:** *P. falciparum* or mixed infection, non-*falciparum* species only **Designated Type:** Type 4 **Batch numbers:** 46050.24.05 **Transport and storage conditions:** Stored below 30 °C **Person(s) performing RDT:** Not stated **RDT setting:** At the study sites (clinic and villages)
Follow-up	Not applicable
Notes	**Source of funding:** Not stated

Table of Methodological Quality

Item	Authors' judgement	Description

Representative spectrum? All tests	Unclear	All participants were all attending clinics or approaching village health workers with fever or history of fever, but the sampling method was not described
Acceptable reference standard? All tests	Unclear	Microscopists viewed 100 high power fields before declaring a slide negative, and results discordant with RDTs were cross-checked. However, it is not clear whether the person doing the cross-checking was a different microscopist working independently
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Yes	"Microscopists were blinded to the rapid test results"
Index test results blinded? All tests	Yes	The RDT was done before the microscopy
Uninterpretable results reported? All tests	Unclear	The number of participants originally enrolled in the study was not explicitly stated; therefore it is unclear whether there were any exclusions due to uninterpretable test results
Withdrawals explained? All tests	Unclear	The number of participants originally enrolled in the study was not explicitly stated; therefore it is unclear whether there were any withdrawals

Van den Broek 2006

Clinical features and settings	**Presenting signs and symptoms:** New episode of suspected malaria, which could include fever, history or other complaints indicating possible malaria infection **Previous treatment for malaria:** Excluded if malaria confirmed (treated or untreated) within the previous four weeks **Clinical setting:** Malaria outpatient centre **Country:** Colombia **Malaria endemicity:** Hypoendemic, annual parasite rate 2% to 5% **Malaria endemic species:** *P. vivax* (54%), *P. falciparum* (46%)
Participants	**Sample size:** 896 **Age:** All ages eligible. Actual numbers of children and adults not stated, although the report mentions that many workers were included. **Sex:** Both males and females eligible. Most of the participants were male (646, 79%) **Co-morbidities and pregnancy:** No exclusion criteria based on co-morbidities. No details of the frequency of these conditions in the participant population is presented. **Parasite density of microscopy positive cases:** Geometric mean approximately 2300 parasites per μl for both *P. falciparum* and *P. vivax*
Study design	Enrollment was prospective. The sampling method was not described. Three RDTs were tested. All individuals received all three tests.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy thick and thin blood smears **Person(s) performing microscopy:** Well trained, experienced microscopists **Microscopy setting:** Not stated **Number of high power fields examined before declaring negative:** At least 200 **Number of observer or repeats:** One, except for about one third of the slides (especially low density parasitaemias and mixed infections). In this case, another microscopist viewed the slide and discordant results between microscopists or between slides and RDTs were sent to the University of Antioquia for external cross-checking. **Resolution of discrepancies between observers:** Disagreements between the internal and external results were sent to a third laboratory: the National Health Institute in Bogota. In cases where both external laboratories disagreed with the internal laboratory, results were corrected accordingly.
Index and comparator tests	**Commerical name of RDT:** Paracheck Pf (Orchid Biomedical Systems, Goa, India) OptiMAL-IT (Diamed AG, Switzerland) NOW Malaria ICT (Binax, Portland, USA) **Parasite(s) designed to detect:** Paracheck Pf - *P. falciparum* OptiMAL-IT - *P. falciparum* or mixed infection, non-*falciparum* species only NOW Malaria ICT - *P. falciparum* or mixed infection, non-*falciparum* species only **Designated Type:** Paracheck Pf - Type 1 OptiMAL - IT - Type 4 Now Malaria ICT - Type 2 **Batch numbers:** Not stated **Transport and storage conditions:** Not described

	Person(s) performing RDT: A bacteriologist. Where the result was ambiguous, two bacteriologists read the test results. **RDT setting:** At the malaria centre
Follow-up	Not applicable
Notes	**Source of funding:** Medicins Sans Frontieres and its donors. The American Society of Tropical Medicine and Hygiene assisted with publication expenses.

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	Unclear	All participants were patients presenting with suspected malaria, but the sampling method was not described
Acceptable reference standard? All tests	No	Microscopists viewed at least 200 high power fields before declaring a slide negative; however the findings were only verified by a second independent reader for a third of slides
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Yes	Report states that microscopists were blinded to the results of RDTs
Index test results blinded? All tests	Yes	Report states that RDTs were blinded to the results of microscopy
Uninterpretable results reported? All tests	Yes	There were no uninterpretable results; and weak lines were scored as positive
Withdrawals explained? All tests	Unclear	The number of participants originally enrolled in the study was not explicitly stated; therefore it was not possible to assess whether there were any withdrawals

Verle 1996

Clinical features and settings	**Presenting signs and symptoms:** Fever or history of fever in previous days **Previous treatment for malaria:** No exclusion criteria based on prior antimalarial drug use. Data collected and reported only for participants who were found to be false positive or true negative (5 out of 6 false positives, 11 out of 65 true negatives) **Clinical setting:** Community health centre. Villagers who felt ill during a malaria epidemic were invited to attend. **Country:** Vietnam (Ha Giang Province Northern Vietnam) **Malaria endemicity:** Mostly hypoendemic, but there is contact with focal areas endemic for malaria, and the study was undertaken during an epidemic **Malaria endemic species:** *P. vivax* and *P. falciparum*
Participants	**Sample size:** 93 **Age:** All ages eligible. Actual numbers of children and adults not stated. **Sex:** Both males and females eligible. Actual numbers of males and females not stated. **Co-morbidities and pregnancy:** No exclusion criteria based on co-morbidities. No details of the frequency of these conditions in the participant population is presented. **Parasite density of microscopy positive cases:** *P. falciparum* geometric mean 6457 parasites per μl, range 2240 to 33,160
Study design	Enrollment was consecutive and prospective. One RDT was tested.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy thick blood smears **Person(s) performing microscopy:** An experienced technician **Microscopy setting:** Not stated **Number of high power fields examined before declaring negative:** 100 **Number of observer or repeats:** One **Resolution of discrepancies between observers:** Not applicable
Index and comparator tests	**Commerical name of RDT:** ParaSight-F (Beckton Dickinson, Franklin Lakes, NJ, SA) **Parasite(s) designed to detect:** *P. falciparum* **Designated Type:** Type 1 **Batch numbers:** Not stated **Transport and storage conditions:** Not described **Person(s) performing RDT:** Not stated **RDT setting:** Community health centre
Follow-up	Not applicable
Notes	**Source of funding:** Belgian Agency for Development Co-operation and the Compagnie Maritime Belge

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	Yes	Participants were a consecutive series of patients attending a health centre with fever during a malaria epidemic

Verle 1996 (*Continued*)

Acceptable reference standard? All tests	No	The microscopist was experienced and viewed at least 100 high power fields, however their findings were not verified by a second independent reader
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Yes	Report states that microscopy was undertaken by a technician unaware of the results of the RDT
Index test results blinded? All tests	Yes	The RDT was undertaken straight away at the health centre, before microscopy results became available
Uninterpretable results reported? All tests	Unclear	The number of participants originally enrolled in the study was not explicitly stated; therefore it was not possible to assess whether there were any exclusions due to uninterpretable test results
Withdrawals explained? All tests	Unclear	The number of participants originally enrolled in the study was not explicitly stated; therefore it was not possible to assess whether there were any withdrawals

Willcox 2009a

Clinical features and settings	**Presenting signs and symptoms:** Symptoms of uncomplicated malaria, primarily fever **Previous treatment for malaria:** No exclusion criteria based on previous antimalarial use, and no data presented on the numbers that previously used antimalarials **Clinical setting:** Village healthworker **Country:** Mali **Malaria endemicity:** Mesoendemic **Malaria endemic species: M**ainly *P. falciparum*
Participants	**Sample size:** 158 under the age of five years (301 total) **Age:** All ages eligible for the study. Refers only to the analysis including children under the age of five years. **Sex:** Both males and females eligible. **Co-morbidities and pregnancy:** No exclusions criteria based on co-morbidities. No

	details of the frequency of these conditions in the participant population are presented. **Parasite density of microscopy positive cases:** Geometric mean 2323 parasites per μl, 95% CI 1492 to 3616
Study design	Enrollment was consecutive and prospective. One RDT was tested.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy thick and thin blood smears **Person(s) performing microscopy:** Experienced microscopists **Microscopy setting:** Field laboratory **Number of high power fields examined before declaring negative:** 100 **Number of observer or repeats:** Two independent microscopists **Resolution of discrepancies between observers:** Cross checked until both microscopists agreed.
Index and comparator tests	**Commerical name of RDT:** Paracheck Pf (Orchid Biomedical Systems, Goa, India) **Parasite(s) designed to detect:** *P. falciparum* **Designated Type:** Type 1 **Batch numbers:** Not stated **Transport and storage conditions:** Stored at room temperatures of up to 40 °C. **Person(s) performing RDT:** A clinician and a laboratory technician from the research team **RDT setting:** Field laboratory
Follow-up	Not applicable
Notes	**Source of funding:** Swiss Agency for Development and Co-operation. Orchid Biomedical Systems supplied the Paracheck Pf tests free of charge.

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	Yes	Participants were a consecutive series of patients presenting with suspected malaria
Acceptable reference standard? All tests	Yes	Two independent experienced microscopists viewed 100 high power fields before declaring a slide negative
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard

Willcox 2009a (*Continued*)

Reference standard results blinded? All tests	Yes	Reported that microscopists were blinded to the results of the RDTs
Index test results blinded? All tests	Yes	Dipsticks were labelled with random numbers so that the people recording the results did not know which people the tests belonged to
Uninterpretable results reported? All tests	Yes	There were no uninterpretable test results (the control line was positive in all cases)
Withdrawals explained? All tests	Yes	The number of participants enrolled was explicitly stated and corresponded to the number presented in the analysis; therefore there were no withdrawals

Willcox 2009b

Clinical features and settings	**Presenting signs and symptoms:** Symptoms of uncomplicated malaria, primarily fever **Previous treatment for malaria:** No exclusion criteria based on previous antimalarial use, and no data presented on the numbers that previously used antimalarials **Clinical setting:** Village health worker **Country:** Mali **Malaria endemicity:** Mesoendemic **Malaria endemic species:** mainly *P. falciparum*
Participants	**Sample size:** 143 aged five or over (301 total) **Age:** All ages included in the study. Refers only to the analysis of participants over the age of five years. **Sex:** Both males and females eligible. **Co-morbidities and pregnancy:** No exclusion criteria based on co-morbidities. No details of the frequency of these conditions in the participant population is presented. **Parasite density of microscopy positive cases:** Geometric mean 267 parasites per μl, 95% CI 172 to 413
Study design	Enrollment was consecutive and prospective. One RDT was tested.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy thick and thin blood smears **Person(s) performing microscopy:** Experienced microscopists **Microscopy setting:** Field laboratory **Number of high power fields examined before declaring negative:** 100 **Number of observer or repeats:** Two independent microscopists **Resolution of discrepancies between observers:** Cross checked until both microscopists agreed.

Index and comparator tests	**Commerical name of RDT:** Paracheck Pf (Orchid Biomedical Systems, Goa, India) **Parasite(s) designed to detect:** *P. falciparum* **Designated Type:** Type 1 **Batch numbers:** Not stated **Transport and storage conditions:** Stored at room temperatures of up to 40°C **Person(s) performing RDT:** A clinician and a laboratory technician from the research team **RDT setting:** Field laboratory
Follow-up	Not applicable
Notes	**Source of funding:** Swiss Agency for Development and Co-operation. Orchid Biomedical Systems supplied the Paracheck Pf tests free of charge.

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	Yes	Participants were a consecutive series of patients presenting with suspected malaria
Acceptable reference standard? All tests	Yes	Two experienced microscopists viewed 100 high power fields before declaring a slide negative
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Yes	Reported that microscopists were blinded to the results of the RDTs
Index test results blinded? All tests	Yes	Dipsticks were labelled with random numbers so that the people recording the results did not know which people the tests belonged to
Uninterpretable results reported? All tests	Yes	There were no uninterpretable test results (the control line was positive in all cases)
Withdrawals explained? All tests	Yes	The number of participants enrolled was explicitly stated and corresponded to the number presented in the analysis; therefore

		there were no withdrawals

Wolday 2001

Clinical features and settings	**Presenting signs and symptoms:** Self-referred to a malaria clinic **Previous treatment for malaria:** No exclusions based on previous antimalarial use; data recorded on previously used antimalarials, but not presented for the sample **Clinical setting:** Malaria clinic **Country:** Ethiopia (Debre Zeit, Addis Ababa) **Malaria endemicity:** Parasite prevalence approximately 40% **Malaria endemic species:** *P. falciparum* and *P. vivax.* The study was undertaken in the season when *P. vivax* predominated.
Participants	**Sample size:** 306 **Age:** All ages included in the study. Range 1 to 70 years, mean age 15.2 years **Sex:** 112 (36.6%) females **Co-morbidities and pregnancy:** No exclusion criteria based on co-morbidities. No details of the frequency of these conditions in the participant population is presented. **Parasite density of microscopy positive cases:** Not presented
Study design	Enrollment was consecutive and prospective. One RDT was tested.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy thick and thin blood smears **Person(s) performing microscopy:** Experienced technicians and parasitologists **Microscopy setting:** Malaria laboratory **Number of high power fields examined before declaring negative:** 300 **Number of observer or repeats:** Two technicians confirmed by two parasitologists **Resolution of discrepancies between observers:** Not stated
Index and comparator tests	**Commerical name of RDT:** Rapid test malaria (Quorum Diagnostics Inc., Vancouver, BC, Canada) **Parasite(s) designed to detect:** *P. falciparum* **Designated Type:** Type 1 **Batch numbers:** Not stated **Transport and storage conditions:** Not stated **Person(s) performing RDT:** Person doing the test not stated. Dipstick readings were done by three independent observers **RDT setting:** Field laboratory
Follow-up	Not applicable
Notes	**Source of funding:** "We thank Quorum Diagnostics Inc (Vancouver, BC, Canada) for the support of this project"

Table of Methodological Quality

Item	Authors' judgement	Description

Wolday 2001 (*Continued*)

Representative spectrum? All tests	Yes	Participants were a consecutive series of patients who had self-referred to a malaria clinic
Acceptable reference standard? All tests	Yes	Two independent, experienced microscopists viewed at least 300 high power fields before declaring a slide negative
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Yes	The blood smears were read before the RDTs
Index test results blinded? All tests	Yes	Report states that blinding was undertaken
Uninterpretable results reported? All tests	Unclear	The number of participants originally enrolled was not explicitly stated; therefore it was not possible to assess whether there were any exclusions due to uninterpretable test results
Withdrawals explained? All tests	Unclear	The number of participants originally enrolled was not explicitly stated; therefore it was not possible to assess whether there were any withdrawals

Wongsrichanalai 1999

Clinical features and settings	**Presenting signs and symptoms:** Symptomatic patients self-referring for initial malaria diagnosis **Previous treatment for malaria:** Participants were excluded if they were known to have taken antimalarial drugs within the last 15 days **Clinical setting:** District malaria clinic and hospital outpatients **Country:** Thailand, on the international borders **Malaria endemicity:** Hypoendemic, with seasonal variation **Malaria endemic species:** *P. falciparum* 50% to 60%, *P. vivax* 40% to 50%
Participants	**Sample size:** 309 **Age:** All age groups eligible. Mean age 29 years. **Sex:** Both males and females eligible. 245 males and 64 females included.

	Co-morbidities and pregnancy: No stated exclusion criteria based on co-morbidities or pregnancy. No details of the frequency of these conditions in the participant population is presented. **Parasite density of microscopy positive cases:** Not presented
Study design	Enrollment was consecutive and prospective. Only one RDT was evaluated.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy thick and thin blood films **Person(s) performing microscopy:** Experienced microscopists **Microscopy setting:** Armed Forces Research Institute of Medical Sciences **Number of high power fields examined before declaring negative:** 200 **Number of observer or repeats:** Two independent microscopists **Resolution of discrepancies between observers:** By a third microscopist, who had the final say
Index and comparator tests	**Commerical name of RDT:** ICT test (AMARD/ ICT, Sydney, Australia) **Parasite(s) designed to detect:** *P. falciparum* **Designated type:** Type 1 **Batch numbers:** Not stated **Trasport and storage conditions:** Not described **Person(s) performing RDT:** Laboratory staff **RDT setting:** The study sites
Follow-up	Not applicable
Notes	**Source of funding:** Half of the RDTs were supplied free of charge by the manufacturer. No other source of funding described.

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	Yes	Participants were a consecutive series of symptomatic new patients self-referring for diagnosis of malaria in an endemic area
Acceptable reference standard? All tests	Yes	Two independent experienced microscopists examined at least 200 high power fields before declaring a slide negative. Discordant results were resolved by a third microscopist in a double-blind manner.
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results

Wongsrichanalai 1999 (*Continued*)

Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Yes	RDTs and microscopy were undertaken at different locations
Index test results blinded? All tests	Yes	RDTs and microscopy were undertaken at different locations
Uninterpretable results reported? All tests	Yes	One RDT failed due to operator error. 100 RDT results were re-read blindly with 100% concordance.
Withdrawals explained? All tests	Yes	The number of participants originally enrolled was explicitly stated and corresponded with the number included in the analysis; therefore there were no withdrawals

Wongsrichanalai 2003

Clinical features and settings	**Presenting signs and symptoms:** Oral temperature over 38 °C, headache or a history of fever in the previous 72 h **Previous treatment for malaria:** No exclusions based on previous episodes or treatment for malaria; no data presented on recent antimalarial use in the children **Clinical setting:** Malaria clinics **Country:** Thailand (Maesod) **Malaria endemicity:** Not stated **Malaria endemic species:** *P. falciparum* and *P. vivax.*
Participants	**Sample size:** 246 **Age:** Inclusion criteria stipulated over 20 years old **Sex:** Both males and females were eligible **Co-morbidities and pregnancy:** Not mentioned, either as an exclusion criteria or characteristic of the included participants **Parasite density of microscopy positive cases:** Not presented
Study design	Enrollment was prospective. The sampling method was not described. One RDT was tested.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy thick and thin blood smears **Person(s) performing microscopy:** Experienced microscopists **Microscopy setting:** Armed Forces Research Institute of Medical Sciences **Number of high power fields examined before declaring negative:** 200 **Number of observer or repeats:** Two independent observers, blinded to each others findings **Resolution of discrepancies between observers:** Resolved by a third expert micro-

	scopist, whose reading was accepted as final. Where there was species discrepancy between microscopy and NOW ICT, PCR was conducted.
Index and comparator tests	**Commerical name of RDT:** NOW ICT Malaria Pf/Pv **Parasite(s) designed to detect:** *P. falciparum* or mixed infection, non-*falciparum* species only **Designated Type:** Type 2 **Batch numbers:** 030611 **Transport and storage conditions:** Not described **Person(s) performing RDT:** Technician **RDT setting:** Armed Forces Research Institute of Medical Sciences
Follow-up	Not applicable
Notes	**Source of funding:** US Army Medical Material Development Activity

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	Unclear	All participants were attending malaria clinics with temperature over 38 °C, headache or a history of fever in the previous 72 h, but the sampling method was not adequately described
Acceptable reference standard? All tests	Yes	Two independent microscopists at a research laboratory viewed at least 200 high power fields before declaring a slide negative
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Yes	"read by two microscopists blinded to.. the NOW ICT results"
Index test results blinded? All tests	Yes	The RDT was carried out before microscopy
Uninterpretable results reported? All tests	Yes	The RDTs had to be repeated in 39 of 285 assays. A successful test was eventually completed for each sample.

Withdrawals explained? All tests	Yes	The number of participants enrolled in the study was clearly stated and corresponded with the number included in the analysis, indicating no withdrawals

Yadav 1997

Clinical features and settings	**Presenting signs and symptoms:** Participants who attended at malaria clinic or who were selected from the villages based on clinical condition **Previous treatment for malaria:** No explicit exclusion criteria based on antimalarial use, and no relevant data presented for included participants **Clinical setting:** Malaria clinic and in the field **Country:** Gujarat, India **Malaria endemicity:** Not stated **Malaria endemic species:** *P. falciparum* and *P. vivax*
Participants	**Sample size:** 148 **Age:** All age groups eligible. Sample included 79 children and 69 adults. **Sex:** 73 males and 75 females included **Co-morbidities and pregnancy:** No stated exclusion criteria based on co-morbidities or pregnancy. No details of the frequency of these conditions in the participant population is presented. **Parasite density of microscopy positive cases:** Not presented
Study design	Enrollment was prospective. The selection and sampling methods were not described. One RDT was evaluated.
Target condition and reference standard(s)	**Target condition:** Malaria parasitaemia **Reference standard:** Microscopy **Person(s) performing microscopy:** Microscopists **Microscopy setting:** Not stated **Number of high power fields examined before declaring negative:** Not stated. The microscopist counted 300 WBCs before declaring a slide negative. A negative slide that tested positive by RDT was re-examined, counting up to 2000 WBCs. **Number of observer or repeats:** A negative slide that tested positive by RDT was re-examined, counting up to 2000 WBCs. A positive slide that tested negative by RDT was re-examined and confirmed by another person by staining the duplicate film. **Resolution of discrepancies between observers:** Not described
Index and comparator tests	**Commerical name of RDT:** ICT test (AMARD/ ICT, Sydney, Australia) **Parasite(s) designed to detect:** *P. falciparum* **Designated type:** Type 1 **Batch numbers:** Not stated **Trasport and storage conditions:** Test kits were carried into the field under cold conditions in the containers that are commonly used for carrying vaccines. **Person(s) performing RDT:** Not states **RDT setting:** Malaria clinic and in the field in villages

Yadav 1997 (*Continued*)

Follow-up	Not applicable
Notes	**Source of funding:** Not stated

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	Unclear	The selection criteria and sampling methods were not described; however all participants had either identified symptoms of malaria or were attending a malaria clinic
Acceptable reference standard? All tests	No	Microscopists did not explicitly view 100 high power fields before declaring a slide negative. However, they had an alternative criteria of 300 WBCs. Re-examination by a second microscopist was done for results discordant for RDT and microscopy.
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference test
Differential verification avoided? All tests	Yes	The same reference test was used regardless of the index test results
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard
Reference standard results blinded? All tests	Unclear	Blinding not described
Index test results blinded? All tests	Yes	The ICT test was performed "blind"
Uninterpretable results reported? All tests	Unclear	The number of participants originally included in the analysis was not explicitly stated; therefore it was not possible to assess whether any participants may have been excluded from the analysis due to uninterpretable test results
Withdrawals explained? All tests	Unclear	The number of participants originally included in the analysis was not explicitly stated; therefore it was not possible to assess whether there were any withdrawals

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
A-Elgayoum 2009 (b)	Not a study of rapid diagnostic tests (compared usual with expert microscopy)
Abul 2000	Participants had cerebral malaria
Afzaal 2001	Review or narrative
Ahmad 2003	Eligibility unclear due to lack of published information
Anonymous 2005	Review or narrative
Ansah 2008	Eligibility unclear due to lack of published information
Araz 2000	Some participants did not have symptoms of malaria
Arcanjo 2007	European foreign language study
Arora 2003	Participants have severe or complicated malaria
Arrospide 2004	European foreign language study
Arrospide 2004 (a)	Majority of participants have no symptoms of malaria
Arrospide 2006	European foreign language study
Ashley 2009	Not able to extract or calculate absolute numbers of true positives, false positives, false negatives and true negatives
Aslan 2001	Participants were hospital inpatients
Assal 1999	Not rapid immunochromatographic tests
Avila 2002	Participants were travellers returning from an endemic to a non-endemic region
Azazy 2004	Only participants with malaria positive blood films by microscopy received the RDT
Babacar 2008	Not a diagnostic test accuracy study
Bartoloni 1998	Single case study
Bassene 2009	Not a diagnostic test accuracy study
Bassett 1991	Not a diagnostic test accuracy study
Beadle 1994	Majority of participants did not have symptoms of malaria

(*Continued*)

Beg 2005	All participants were positive for malaria by microscopy
Belizario 2005	Participants were recruited by active case finding
Bell 2005	Not a consecutive sample: excluded a random sample of participants who were negative for malaria by microscopy
Bell 2006	Review or narrative
Bellagra 1998	Participants are travellers returning from an endemic to a non-endemic area
Bendezu 2008	Not able to extract or calculate absolute numbers of true positives, false positives, false negatives and true negatives
Berens-Riha 2009	Participants were dead
Bhandari 2008	All participants were positive for malaria by microscopy
Bhatt 1994	Review or narrative
Birku 1999	Participants had severe or complicated malaria
Bisoffi 2009	Not a diagnostic test accuracy study
Bisoffi 2009a	Review or narrative
Biswas 2004	Not a diagnostic test accuracy study
Biswas 2006	Not an immunochromatographic test
Bouchaud 2000	Participants were travellers returning from endemic to non-endemic areas
Brenier-Pinchart 2000	Participants were travellers returning from endemic to non-endemic areas
Bruxvoort 2008	Participants were recruited by active case finding
Bualombai 2003	No usable data for *P. falciparum* malaria
Bualombai 2006	Eligibility unclear due to lack of published information
Buchachart 2004	Participants are hospital in-patients
Bujanover 2002	Not a diagnostic test accuracy study
Cabezas 2004	Not a diagnostic test accuracy study (compares 'field' and laboratory RDT results)
Cavallo 1997	Participants are travellers returning from an endemic to a non-endemic area

(*Continued*)

Chatterjee 2008	Eligibility unclear due to lack of published information
Cheng 2006	Review or narrative
Chilton 2006	Not a diagnostic test accuracy study
Chiodini 1998	Review or narrative
Chiodini 2005	Not a diagnostic test accuracy study
Cho 2001	Not undertaken in a malaria endemic area
Coleman 2002a	Majority of participants did not have symptoms of malaria
Coleman 2002b	Majority of participants did not have symptoms of malaria
Cong Le 2002	Article written in Russian only
Craig 1997	Tested blood films with artificially cultured and diluted malaria parasites
Craig 2002	The participants were positive for malaria by microscopy
Cropley 2000	Participants were travellers returning from endemic to non-endemic areas
Cuadros 2007	Participants were travellers returning from endemic to non-endemic areas
De Carsalade 2009	European foreign language study
De Dominguez 1996	Not a diagnostic test accuracy study
De Monbrison 2004	Participants were travellers returning from endemic to non-endemic areas
Delaunay 2008	Review or narrative
Deletoille 1987	Participants are travellers returning from an endemic to a non-endemic area
Di Perry 1997	All participants were positive for malaria by microscopy
Dietze 1995	Some participants did not have symptoms of malaria
Drakeley 2009	Review or narrative
Dubarry 1990	Not evaluating an immunochromatographic rapid diagnostic test
Durand 2005	Participants were travellers returning from endemic to non-endemic areas
Durand 2005a	Review or narrative

(*Continued*)

Dyer 2000	All participants were positive for malaria by microscopy
Eisen 2000	Not undertaken in a malaria endemic area
El-Moamly 2007	Participants were travellers returning from a malaria endemic to a non-endemic area
Elmardi 2009	Not a diagnostic test accuracy study
Endeshaw 2008	Majority of participants did not have symptoms of malaria
Fan 2000	Written in Chinese only
Farcas 2003	Participants were travellers returning from endemic to non-endemic areas
Farcas 2004	Not an immunochromatographic test
Ferro 2002	Participants were travellers returning from an endemic area to a non-endemic area
Figueiredo 2003	All participants were positive for malaria by microscopy
Fogg 2008	No usable data for *P. falciparum* malaria
Fryauff 1997	Eligibility unclear due to lack of published information
Fryauff 2000	Participants did not have symptoms of malaria
Funk 1999	Participants were travellers returning from endemic to non-endemic areas
Garavelli 2002	Participants were travellers returning from endemic to non-endemic areas
Garcia 1996	Eligibility unclear due to lack of published information
Gatti 2002	Participants were travellers returning from endemic to non-endemic areas
Gatti 2007	Participants were travellers returning from endemic to non-endemic areas
Ghanchi 2009	Not a diagnostic test accuracy study
Gillet 2009 (a)	Participants were travellers returning from endemic to non-endemic areas
Gillet 2009 (b)	Not a diagnostic test accuracy study
Gillet 2009 (c)	Participants were travellers returning from an endemic to a non-endemic area
Gogtay 1999	Participants had severe or complicated malaria

(*Continued*)

Gogtay 2003	Participants were all positive for malaria by blood smear
Gonzales-Ceron 2005	Evaluates *P. vivax* only
Grobusch 1999	Not undertaken in a malaria endemic area
Grobusch 2002	Not undertaken in a malaria endemic area
Grobusch 2003	Participants were travellers returning from endemic to non-endemic areas
Grobusch 2003b	Participants were travellers returning from endemic to non-endemic areas
Gupta 2001	Some participants had severe or complicated malaria
Gutierrez 2005	Not a diagnostic test accuracy study
Haditsch 2004	Review or narrative
Hance 2005	Review or narrative
Hanscheid 1999	Review or narrative
Happi 2004	All participants were positive for malaria by microscopy
Hashizume 2006	Participants were displaced persons from mainly very low endemicity areas
Hernandes 2001	Participants were travellers returning from endemic to non-endemic areas
Holmberg 1992	Not a diagnostic test accuracy study
Hossain 2008	Participants had severe or complicated malaria
Houze 2009	All participants were positive for malaria by microscopy
Humar 1997	Participants were travellers returning from endemic to non-endemic areas
Huong 2002	Not based on a consecutive sample; included a group malaria positive by microscopy, and an asymptomatic malaria negative control group
Iqbal 2000	Not a consecutive sample: participants were selected to have a high risk of rheumatoid factor
Iqbal 2001	Participants were travellers returning from endemic to non-endemic areas
Iqbal 2002	Participants were travellers returning from endemic to non-endemic areas
Iqbal 2004	All participants were positive for malaria by microscopy

(*Continued*)

Jelinek 1996	Does not evaluate an immunochromatographic rapid diagnostic test for malaria
Jelinek 1999	Participants were travellers returning from endemic to non-endemic areas
Jelinek 2000	Participants were travellers returning from endemic to non-endemic areas
Jelinek 2001	Participants were travellers returning from endemic to non-endemic areas
Jeurissen 1999	Review or narrative
John 1998	All participants were positive for malaria by microscopy
Joshi 2004	Not evaluating an immunochromatographic rapid diagnostic test
Kaewsonthi 1996	Not a diagnostic test accuracy study
Kahama-Maro 2008	Eligibility unclear due to lack of published information
Kakkilaya 2003	Review or narrative
Kamugisha 2008	Majority of participants did not have symptoms of malaria
Karbwang 1996	All participants were positive for malaria by microscopy
Kaur 2000	All participants had cerebral malaria
Kaushal 1995	Tested for *P. knowlesi* infection in monkeys
Kaushal 1997	Review or narrative
Kawai 2009	Tested for *P. knowlesi* infection in monkeys
Keating 2009	Majority of participants did not have symptoms of malaria
Khairnar 2009	Participants were travellers returning from an endemic to a non-endemic area
Khan 2004	Participants were hospital inpatients
Kilian 1997	Not able to extract or calculate absolute numbers of true positives, false positives, false negatives and true negatives
Kim 2008	Includes a symptomatic group with malaria infection identified by microscopy, and an asymptomatic group with no malaria infection by microscopy
Knappik 2002	Participants were travellers returning from endemic to non-endemic areas
Kodisinghe 1997	Some participants did not have symptoms of malaria

(*Continued*)

Kumar 2000	Participants were migrants from a very low endemicity area
Lee 1999	Some participants did not have symptoms of malaria
Lee 2008	Participants were soldiers usually residing in non-endemic areas
Lema 1999	Some participants were attending for follow-up of a previously diagnosed and treated case of malaria
Lepere 2004	Not a diagnostic test accuracy study
Lim 2001	Half the participants had malaria confirmed by microscopy before enrolment
Llanos Zavalaga 2000	Not a diagnostic test accuracy study
Llanos-Zavalaga 2002	European foreign language study
Mahajan 2000	Participants were hospital inpatients
Makler 1998	Review or narrative
Makler 2009	Review or narrative
Malik 2004	Study was based at a tertiary referral centre with a high percentage of patients with complicated malaria
Mankhambo 2002	Majority of participants did not have symptoms of malaria
Mason 2002	Some participants did not have symptoms of malaria
Mayxay 2004	Not able to extract or calculate absolute numbers of true positives, false positives, false negatives and true negatives
McCutchan 2008	Review or narrative
Meena 2009	Participants were all hospital inpatients
Menan 1996	Not a study of rapid diagnostic tests
Mendoza 2007	Eligibility unclear due to lack of published information
Mengesha 1999	Not able to extract or calculate absolute numbers of true positives, false positives, false negatives and true negatives
Metzger 2008	Participants were recruited by active case finding
Mharakurwa 1997	Participants had all been recently treated for malaria
Miller 2001	Letter

(*Continued*)

Miller 2008	Not able to extract or calculate absolute numbers of true positives, false positives, false negatives and true negatives
Mills 1999	Participants were travellers returning from endemic to non-endemic areas
Mills 2007	Eligibility unclear due to lack of published information
Mills 2009	Not a consecutive sample; selected HIV positive participants only
Minodier 2005	Review or narrative
Mishra 1999	Not a consecutive sample; comprised a malaria positive group by microscopy, and negative control groups
Mishra 2007	Eligibility unclear due to lack of published information
Mohanty 1999	Eligibility unclear due to lack of published information
Montoya 2008	European foreign language study
Moody 2000	Participants were travellers returning from endemic to non-endemic areas
Moody 2002	Review or narrative
Moody 2002a	RDTs tested on artificially cultured blood samples
Moonasar 2007	Not a diagnostic test accuracy study
Moulin 2009	Review or narrative
Mueller 2007	Participants not representative of people presenting to ambulatory care setting with symptoms of malaria
Munier 2009	European foreign language study
Murray 2003	Review or narrative
Murray 2008	Review or narrative
Myjak 2004	Participants were travellers returning from endemic to non-endemic areas
Naing 2002	No usable data for *P. falciparum* malaria
Nema 2004	All participants were positive for malaria by microscopy
Neumann 2008	Majority of participants did not have symptoms of malaria
Ochola 2006	Review or narrative

(*Continued*)

OMS 1999	Not a diagnostic test accuracy study
Onile 2005	Review or narrative
Ozbilge 2006	Not an immunochromatographic test
Pabon 2007	European foreign language study
Palmer 1998	Eligibility unclear due to lack of published information
Palmer 1999	All participants were positive for malaria by microscopy
Palmer 2003	Participants were travellers returning from endemic to non-endemic areas
Pammenter 1988	Review or narrative
Pandey 1995	Review or narrative
Park 2003	Not a consecutive sample; included a known malaria group and negative control group by microscopy
Park 2006	Written in Korean only
Parra 1991	Not a diagnostic test accuracy study
Penhalbel 2005	Not a consecutive sample; included a known malaria group and negative control group by microscopy
Perez 2007	Review or narrative
Peyron 1999	Review or narrative
Pica 2005	Review or narrative
Pieroni 1998	Participants were travellers returning from endemic to non-endemic areas
Pinto 1999	All participants had previously tested negative for malaria and had symptoms that meant complicated malaria could not be ruled out
Piper 1999	Half the participants lived in non-endemic areas
Pividal 1994	Not a diagnostic test accuracy study (blood samples from one patient were serially diluted and tested)
Planche 2001	Review or narrative
Playford 2002	Participants were travellers returning from endemic to non-endemic areas
Popov 2000	Written in Russian only

(*Continued*)

Popov 2004	Written in Russian only
Premji 1994	Participants did not have symptoms of malaria
Prou 1988	Not an immunochromatographic test
Proux 2001	Majority of participants did not have symptoms of malaria
Quintana 1998	Eligibility unclear due to lack of published information
Rabinovich 2006	Written in Russian only
Radrianasolo 2007	European foreign language study
Rahim 2002	All participants were positive for malaria by microscopy
Rajendran 2006	Eligibility unclear due to lack of published information
Ratnawati 2008	Many participants were recruited by active case finding
Rehlis 2004	Written in Polish only
Reyburn 2007	Not a diagnostic test accuracy study
Ricci 2000	Participants were travellers returning from endemic to non-endemic areas
Richardson 2002	Participants were travellers returning from endemic to non-endemic areas
Richter 2004	Review or narrative
Richter 2004a	Participants were travellers returning from endemic to non-endemic areas
Roche 1995	Not an immunochromatographic test
Rodriguez-Iglesias 2005	Review or narrative
Rodulfo 2007	Some of the participants did not have symptoms of malaria
Rolland 2006	Not a diagnostic test accuracy study
Rubio 2001	Participants were travellers returning from endemic to non-endemic areas
Ryan 2002	Not a diagnostic test accuracy study
Samal 1998	Not an immunochromatographic test

(*Continued*)

Saranya 2003	Review or narrative
Schmidt 2003	Review or narrative
Seidahmed 2008	Not a diagnostic test accuracy study
Sezibera 2009	Not a diagnostic test accuracy study
Shah 2004	All participants were positive for malaria by microscopy
Shamsi 1999	Eligibility unclear due to lack of published information
Sharma 2008	Some participants did not have symptoms of malaria
She 2007	Not undertaken in a malaria endemic area
Shenoi 1996	Eligibility unclear due to lack of published information
Shiff 1993	Some participants did not have symptoms of malaria
Shillcutt 2008	Not a diagnostic test accuracy study
Shirayama 2008	Not a diagnostic test accuracy study
Shujatullah 2006	Participants had severe or complicated malaria
Shujatullah 2009	Participants were hospital inpatients
Singer 2004	Majority of participants did not have symptoms of malaria
Singh 2000 (b)	Some participants did not have symptoms of malaria
Singh 2001	Participants were recruited by active case finding
Singh 2002	Majority of participants did not have symptoms of malaria
Singh 2002(b)	All participants were positive for malaria by microscopy
Singh 2004	Participants had severe or complicated malaria
Singh 2005 (a)	Majority of participants did not have symptoms of malaria
Singh 2005 (b)	Not able to extract or calculate absolute numbers of true positives, false positives, false negatives and true negatives
Singh 2005c	Some participants did not have symptoms of malaria

(*Continued*)

Singh 2007	Majority of participants did not have symptoms of malaria
Skarbinski 2009	Not a diagnostic test accuracy study
Smego 2000	Review or narrative
Sotimehin 2007	Majority of participants did not have symptoms of malaria
Srinivasan 2000	Participants were travellers returning from endemic to non-endemic areas
Stauffer 2005	Participants were refugees from an endemic to a non-endemic country
Stauffer 2006	Participants were travellers returning from endemic to non-endemic areas
Stauffer 2009	Participants were all travellers returning from an endemic to a non-endemic area
Sturenburg 2009	Review or narrative
Susi 2005	Participants were all travellers returning from an endemic to a non-endemic area
Swarthout 2007	All participants were positive for malaria by microscopy
Tagbor 2008	Majority of participants did not have symptoms of malaria
Tarazona 2004	Not able to extract or calculate absolute numbers of true positives, false positives, false negatives and true negatives
Tarimo 1999	Not able to extract or calculate absolute numbers of true positives, false positives, false negatives and true negatives
Tarimo 2001	Not able to extract or calculate absolute numbers of true positives, false positives, false negatives and true negatives
Taylor 2002	All participants were positive for malaria by microscopy
Tham 1999	Participants were all travellers returning from an endemic to a non-endemic area
Thepsamarn 1997	All participants were positive for malaria by microscopy
Tietche 1996	Not a diagnostic test accuracy study (study of the probability of malaria in febrile children)
Tjitra 2001a	All participants were positive for malaria by microscopy
Tjitra 2001b	All participants were positive for malaria by microscopy
Trachsler 1999	Not a diagnostic test accuracy study

(*Continued*)

Uguen 1995	Participants were travellers returning from endemic to non-endemic areas
Uneke 2008	Not a diagnostic test accuracy study
Uneke 2008a	Review or narrative
Uzuchukwu 2009	No usable data for *P. falciparum* malaria
Valea 2009	No usable data for *P. falciparum* malaria
Valecha 1998	Eligibility unclear due to lack of published information
Valecha 2002	Participants were recruited by active case finding
Van den Ende 1998	Participants were travellers returning from endemic to non-endemic areas
Van der Palen 2009	Participants were travellers returning from endemic to non-endemic areas
Van Dijk 2009	Participants are travellers returning from an endemic to a non-endemic area
Van Hellemond 2009	Not a diagnostic test accuracy study
VanderJagt 2005	Majority of participants had no symptoms of malaria
Venkatesh 2007	Participants had severe or complicated malaria
Voller 1993	Review or narrative
Waltz 2007	Review or narrative
Wang J-Y 2007	Not a commercial test kit
Wanji 2008	Participants did not have symptoms of malaria
WHO 1996	Review or narrative
Wiese 2006	Participants were travellers returning from endemic to non-endemic areas
Williams 2008	Not a diagnostic test accuracy study
Win 2001	Review or narrative
Wongsrichanalai 2001	Review or narrative
Wongsrichanalai 2007	Review or narrative
Wu 2005	Not an immunochromatographic rapid diagnostic test kit

(*Continued*)

Yavo 2002	European foreign language study
Zakai 2003	Review or narrative
Zerpa 2007	Not able to extract or calculate absolute numbers of true positives, false positives, false negatives and true negatives
Zheng 1999	Written in Chinese only
Zhu 1998	Written in Chinese only
Zikusooka 2008	Not a diagnostic test accuracy study
Zurovac 2008	Not a diagnostic test accuracy study

DATA

Presented below are all the data for all of the tests entered into the review.

Tests. Data tables by test

Test	No. of studies	No. of participants
1 Paracheck-Pf	27	22319
2 ParaSight-F	17	12521
3 ICT Malaria Pf	16	2955
4 ParaHIT-F	4	1119
5 PATH	2	378
6 Determine Malaria Pf	1	526
7 Rapid Test Malaria	1	306
8 Diaspot Malaria	1	153
9 New Pf-1 mini	1	10
10 Hexagon Malaria	1	119
11 Type 1 (All)	65	40062
12 CareStart Malaria Pf/Pan	2	537
13 ICT Malaria Pf/Pv	6	2255
14 NOW malaria ICT	2	1142
15 Type 2 (All)	8	3397
16 SD Malaria Antigen Bioline	2	224
17 First Response Malaria	1	291
18 OptiMAL/ OptiMAL 48	10	3393
19 Parascreen	2	443
20 Type 3 (All)	5	958
21 OptiMAL-IT	3	1356
22 Parabank	2	7918
23 Type 4 (All)	16	13010
24 Carestart Pf/Pv	2	908
25 ParaSight Pf/Pv	1	869
26 Type 5 (All)	3	1777
27 HRP-2 based tests	75	43307
28 pLDH based tests	19	14787
29 Type 1 (paired comparison with Type 4)	7	9764
30 Type 4 (paired comparison with Type 1)	7	9761
31 PCR adjusted microscopy, Type 1, Paracheck-PF (All)	1	7000
32 PCR adjusted microscopy, Type 4, Parabank (All)	1	7000
33 PCR, Type 1, ParaSight-F	1	520
34 PCR, Type 1, ParaHIT-F	1	336
35 PCR, Type 1 (All)	2	856
36 PCR, Type 3, SD Malaria Antigen (All)	1	198
37 HRP-2 based tests paired data	9	10626

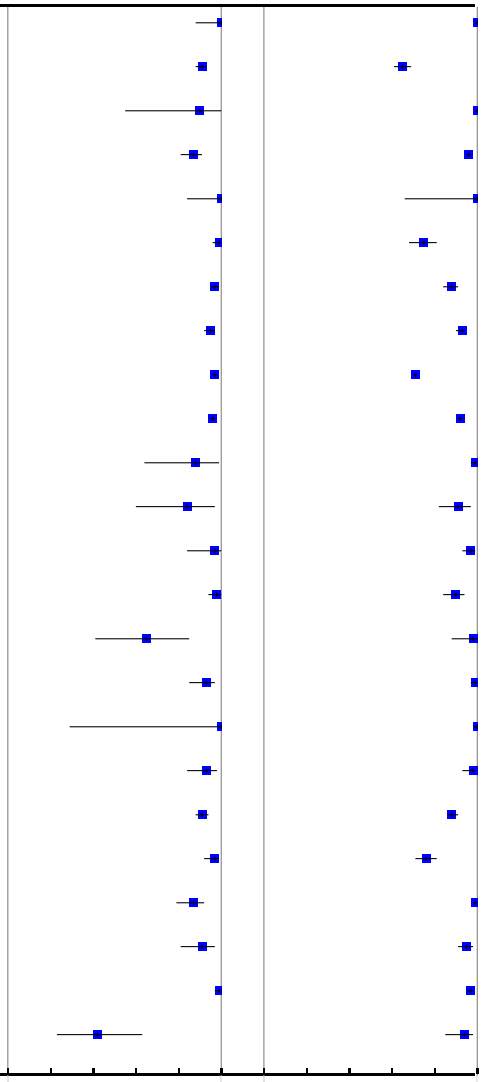
38 pLDH based tests paired data	9	10623
71 PCR, Type 6, PALUTOP (All)	1	313
72 PCR, Type 4, OptiMAL-IT (All)	1	313

Test 1. Paracheck-Pf.

Review: Rapid diagnostic tests for diagnosing uncomplicated *P. falciparum* malaria in endemic countries

Test: 1 Paracheck-Pf

Study	TP	FP	FN	TN	Sensitivity	Specificity
A-Elgayoum 2009	28	0	0	382	1.00 [0.88, 1.00]	1.00 [0.99, 1.00]
Abeku 2008a	554	220	55	408	0.91 [0.88, 0.93]	0.65 [0.61, 0.69]
Abeku 2008b	9	1	1	989	0.90 [0.55, 1.00]	1.00 [0.99, 1.00]
De Oliveira 2009	163	65	25	1574	0.87 [0.81, 0.91]	0.96 [0.95, 0.97]
Dev 2004	21	0	0	9	1.00 [0.84, 1.00]	1.00 [0.66, 1.00]
Gerstl 2009	167	44	2	130	0.99 [0.96, 1.00]	0.75 [0.68, 0.81]
Guthmann 2002	412	38	11	280	0.97 [0.95, 0.99]	0.88 [0.84, 0.91]
Hopkins 2007	274	47	15	582	0.95 [0.92, 0.97]	0.93 [0.90, 0.94]
Hopkins 2008a	2626	1245	77	3052	0.97 [0.96, 0.98]	0.71 [0.70, 0.72]
Kumar 2004	837	161	34	1859	0.96 [0.95, 0.97]	0.92 [0.91, 0.93]
Mboera 2006a	15	4	2	287	0.88 [0.64, 0.99]	0.99 [0.97, 1.00]
Mboera 2006b	16	6	3	63	0.84 [0.60, 0.97]	0.91 [0.82, 0.97]
Mboera 2006c	31	6	1	190	0.97 [0.84, 1.00]	0.97 [0.93, 0.99]
Mboera 2006d	147	16	3	140	0.98 [0.94, 1.00]	0.90 [0.84, 0.94]
Mboera 2006e	13	1	7	43	0.65 [0.41, 0.85]	0.98 [0.88, 1.00]
Mendiratta 2006	75	5	6	357	0.93 [0.85, 0.97]	0.99 [0.97, 1.00]
Mens 2007a	3	0	0	151	1.00 [0.29, 1.00]	1.00 [0.98, 1.00]
Mens 2007b	56	3	4	121	0.93 [0.84, 0.98]	0.98 [0.93, 0.99]
Msellem 2009	279	82	26	618	0.91 [0.88, 0.94]	0.88 [0.86, 0.91]
Nigussie 2008a	147	72	5	228	0.97 [0.92, 0.99]	0.76 [0.71, 0.81]
Pandya 2001	98	2	15	352	0.87 [0.79, 0.92]	0.99 [0.98, 1.00]
Pattanasin 2003	52	10	5	202	0.91 [0.81, 0.97]	0.95 [0.91, 0.98]
Sharew 2009	167	16	1	484	0.99 [0.97, 1.00]	0.97 [0.95, 0.98]
Tagbo 2007	11	4	15	59	0.42 [0.23, 0.63]	0.94 [0.85, 0.98]



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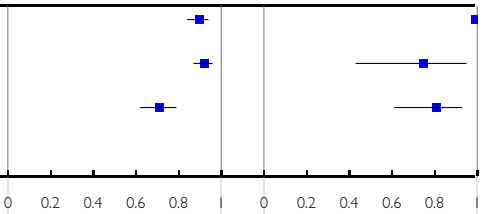
Study	TP	FP	FN	TN	Sensitivity	Specificity
Van den Broek 2006	137	4	15	740	0.90 [0.84, 0.94]	0.99 [0.99, 1.00]
Willcox 2009a	135	3	11	9	0.92 [0.87, 0.96]	0.75 [0.43, 0.95]
Willcox 2009b	83	5	34	21	0.71 [0.62, 0.79]	0.81 [0.61, 0.93]

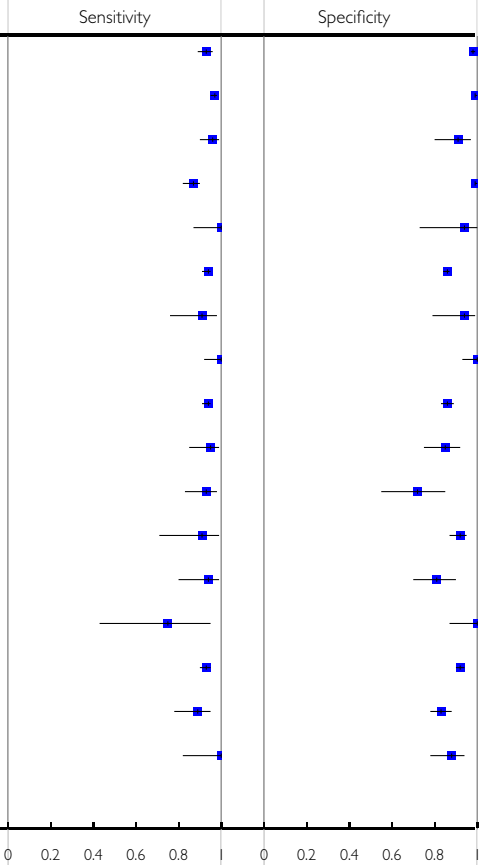


Test 2. ParaSight-F.

Review: Rapid diagnostic tests for diagnosing uncomplicated *P. falciparum* malaria in endemic countries

Test: 2 ParaSight-F

Study	TP	FP	FN	TN	Sensitivity	Specificity
Banchongaksorn 1996a	226	12	16	659	0.93 [0.89, 0.96]	0.98 [0.97, 0.99]
Banchongaksorn 1997	598	20	21	2722	0.97 [0.95, 0.98]	0.99 [0.99, 1.00]
Bojang 1999	82	5	3	49	0.96 [0.90, 0.99]	0.91 [0.80, 0.97]
Caraballo 1996	268	8	41	1081	0.87 [0.82, 0.90]	0.99 [0.99, 1.00]
Dev 2004	26	1	0	17	1.00 [0.87, 1.00]	0.94 [0.73, 1.00]
Forney 2001	541	346	37	2057	0.94 [0.91, 0.95]	0.86 [0.84, 0.87]
Gaye 1998	31	2	3	30	0.91 [0.76, 0.98]	0.94 [0.79, 0.99]
Kar 1998	45	0	0	48	1.00 [0.92, 1.00]	1.00 [0.93, 1.00]
Kilian 1999	635	89	44	558	0.94 [0.91, 0.95]	0.86 [0.83, 0.89]
Mharakurwa 1997a	54	12	3	67	0.95 [0.85, 0.99]	0.85 [0.75, 0.92]
Mharakurwa 1997b	53	11	4	28	0.93 [0.83, 0.98]	0.72 [0.55, 0.85]
Mharakurwa 1997c	20	16	2	175	0.91 [0.71, 0.99]	0.92 [0.87, 0.95]
Murahwa 1999	31	12	2	52	0.94 [0.80, 0.99]	0.81 [0.70, 0.90]
Omar 1999	9	0	3	26	0.75 [0.43, 0.95]	1.00 [0.87, 1.00]
Singh 1997 (b)	354	64	28	785	0.93 [0.90, 0.95]	0.92 [0.90, 0.94]
Stephens 1999	55	39	7	195	0.89 [0.78, 0.95]	0.83 [0.78, 0.88]
Verle 1996	19	9	0	65	1.00 [0.82, 1.00]	0.88 [0.78, 0.94]

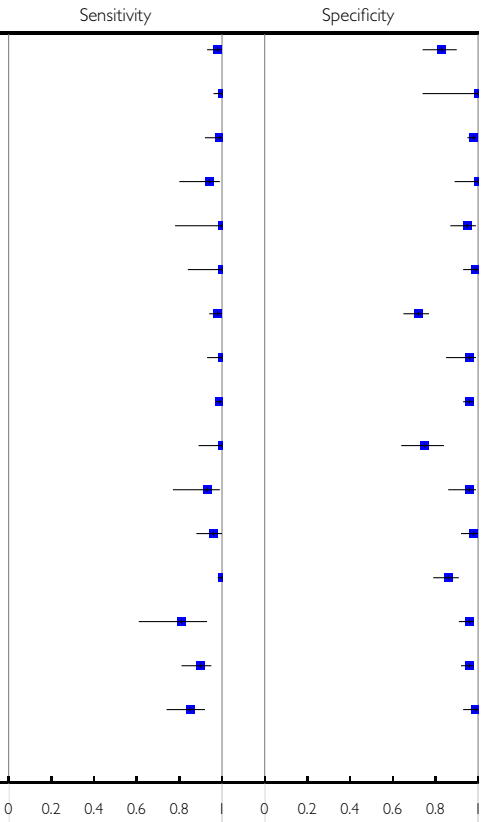


Test 3. ICT Malaria Pf.

Review: Rapid diagnostic tests for diagnosing uncomplicated *P. falciparum* malaria in endemic countries

Test: 3 ICT Malaria Pf

Study	TP	FP	FN	TN	Sensitivity	Specificity
Bechem 1999	98	17	2	82	0.98 [0.93, 1.00]	0.83 [0.74, 0.90]
Dev 2004	85	0	0	12	1.00 [0.96, 1.00]	1.00 [0.74, 1.00]
Durrheim 1998	68	4	1	191	0.99 [0.92, 1.00]	0.98 [0.95, 0.99]
Gaye 1998	32	0	2	32	0.94 [0.80, 0.99]	1.00 [0.89, 1.00]
Ghosh 2000	15	3	0	63	1.00 [0.78, 1.00]	0.95 [0.87, 0.99]
Kumar 1996	21	1	0	76	1.00 [0.84, 1.00]	0.99 [0.93, 1.00]
Kyabayinze 2008	136	62	3	156	0.98 [0.94, 1.00]	0.72 [0.65, 0.77]
Mohapatra 1996	53	2	0	45	1.00 [0.93, 1.00]	0.96 [0.85, 0.99]
Moonasar 2009	190	8	1	206	0.99 [0.97, 1.00]	0.96 [0.93, 0.98]
Murahwa 1999	33	21	0	63	1.00 [0.89, 1.00]	0.75 [0.64, 0.84]
Nwuba 2001	27	2	2	46	0.93 [0.77, 0.99]	0.96 [0.86, 0.99]
Sharma 1999	54	1	2	63	0.96 [0.88, 1.00]	0.98 [0.92, 1.00]
Singh 1997 (a)	201	22	0	130	1.00 [0.98, 1.00]	0.86 [0.79, 0.91]
Stow 1999	21	6	5	132	0.81 [0.61, 0.93]	0.96 [0.91, 0.98]
Wongsrichanalai 1999	69	10	8	222	0.90 [0.81, 0.95]	0.96 [0.92, 0.98]
Yadav 1997	60	1	11	76	0.85 [0.74, 0.92]	0.99 [0.93, 1.00]

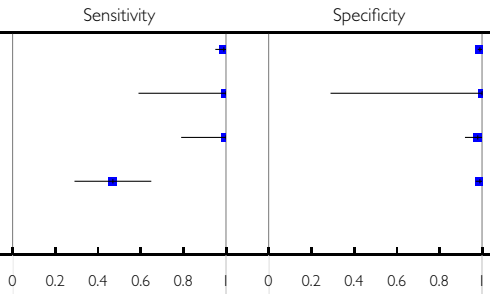


Test 4. ParaHIT-F.

Review: Rapid diagnostic tests for diagnosing uncomplicated *P. falciparum* malaria in endemic countries

Test: 4 ParaHIT-F

Study	TP	FP	FN	TN	Sensitivity	Specificity
Chitkara 2004	135	5	2	531	0.99 [0.95, 1.00]	0.99 [0.98, 1.00]
Dev 2004	7	0	0	3	1.00 [0.59, 1.00]	1.00 [0.29, 1.00]
Devi 2002	16	2	0	82	1.00 [0.79, 1.00]	0.98 [0.92, 1.00]
Nicastri 2009a	15	3	17	301	0.47 [0.29, 0.65]	0.99 [0.97, 1.00]

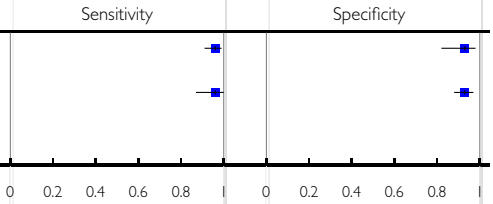


Test 5. PATH.

Review: Rapid diagnostic tests for diagnosing uncomplicated *P. falciparum* malaria in endemic countries

Test: 5 PATH

Study	TP	FP	FN	TN	Sensitivity	Specificity
Gaye 1999	122	4	5	51	0.96 [0.91, 0.99]	0.93 [0.82, 0.98]
Labbe 2001	51	10	2	133	0.96 [0.87, 1.00]	0.93 [0.88, 0.97]

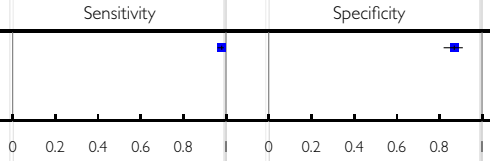


Test 6. Determine Malaria Pf.

Review: Rapid diagnostic tests for diagnosing uncomplicated *P. falciparum* malaria in endemic countries

Test: 6 Determine Malaria Pf

Study	TP	FP	FN	TN	Sensitivity	Specificity
Singh 2000 (a)	257	35	5	229	0.98 [0.96, 0.99]	0.87 [0.82, 0.91]

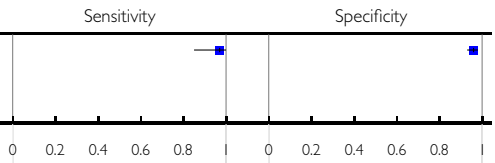


Test 7. Rapid Test Malaria.

Review: Rapid diagnostic tests for diagnosing uncomplicated *P. falciparum* malaria in endemic countries

Test: 7 Rapid Test Malaria

Study	TP	FP	FN	TN	Sensitivity	Specificity
Wolday 2001	35	11	1	259	0.97 [0.85, 1.00]	0.96 [0.93, 0.98]

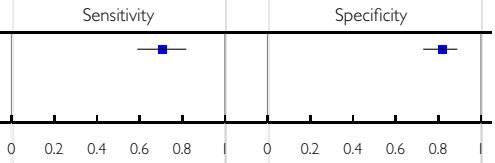


Test 8. Diaspot Malaria.

Review: Rapid diagnostic tests for diagnosing uncomplicated *P. falciparum* malaria in endemic countries

Test: 8 Diaspot Malaria

Study	TP	FP	FN	TN	Sensitivity	Specificity
Sayang 2009	45	16	18	74	0.71 [0.59, 0.82]	0.82 [0.73, 0.89]

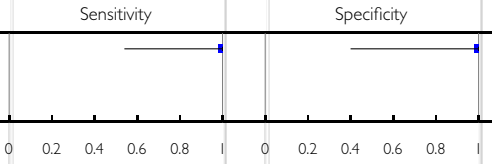


Test 9. New Pf-1 mini.

Review: Rapid diagnostic tests for diagnosing uncomplicated *P. falciparum* malaria in endemic countries

Test: 9 New Pf-1 mini

Study	TP	FP	FN	TN	Sensitivity	Specificity
Dev 2004	6	0	0	4	1.00 [0.54, 1.00]	1.00 [0.40, 1.00]

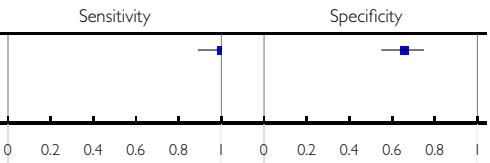


Test 10. Hexagon Malaria.

Review: Rapid diagnostic tests for diagnosing uncomplicated *P. falciparum* malaria in endemic countries

Test: 10 Hexagon Malaria

Study	TP	FP	FN	TN	Sensitivity	Specificity
Mwanza 2005	32	30	0	57	1.00 [0.89, 1.00]	0.66 [0.55, 0.75]

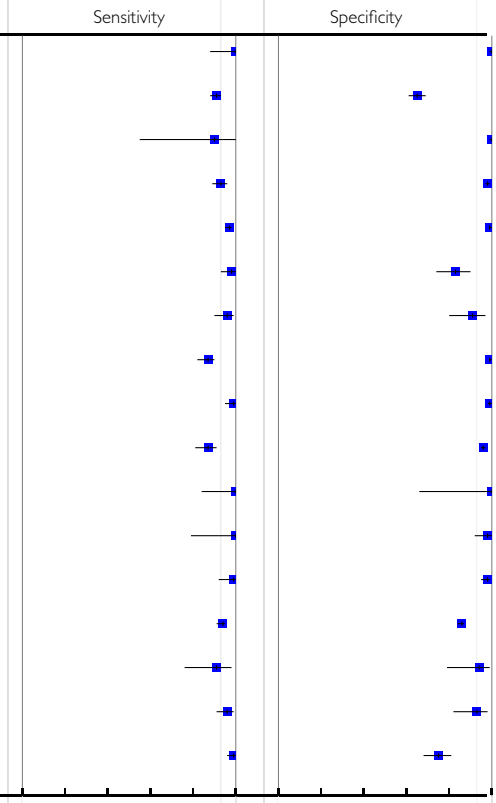


Test 11. Type 1 (All).

Review: Rapid diagnostic tests for diagnosing uncomplicated *P. falciparum* malaria in endemic countries

Test: 11 Type 1 (All)

Study	TP	FP	FN	TN	Sensitivity	Specificity
A-Elgayoum 2009	28	0	0	382	1.00 [0.88, 1.00]	1.00 [0.99, 1.00]
Abeku 2008a	554	220	55	408	0.91 [0.88, 0.93]	0.65 [0.61, 0.69]
Abeku 2008b	9	1	1	989	0.90 [0.55, 1.00]	1.00 [0.99, 1.00]
Banchongaksorn 1996a	226	12	16	659	0.93 [0.89, 0.96]	0.98 [0.97, 0.99]
Banchongaksorn 1997	598	20	21	2722	0.97 [0.95, 0.98]	0.99 [0.99, 1.00]
Bechem 1999	98	17	2	82	0.98 [0.93, 1.00]	0.83 [0.74, 0.90]
Bojang 1999	82	5	3	49	0.96 [0.90, 0.99]	0.91 [0.80, 0.97]
Caraballo 1996	268	8	41	1081	0.87 [0.82, 0.90]	0.99 [0.99, 1.00]
Chitkara 2004	135	5	2	531	0.99 [0.95, 1.00]	0.99 [0.98, 1.00]
De Oliveira 2009	163	65	25	1574	0.87 [0.81, 0.91]	0.96 [0.95, 0.97]
Dev 2004	21	0	0	9	1.00 [0.84, 1.00]	1.00 [0.66, 1.00]
Devi 2002	16	2	0	82	1.00 [0.79, 1.00]	0.98 [0.92, 1.00]
Durrheim 1998	68	4	1	191	0.99 [0.92, 1.00]	0.98 [0.95, 0.99]
Forney 2001	541	346	37	2057	0.94 [0.91, 0.95]	0.86 [0.84, 0.87]
Gaye 1998	31	2	3	30	0.91 [0.76, 0.98]	0.94 [0.79, 0.99]
Gaye 1999	122	4	5	51	0.96 [0.91, 0.99]	0.93 [0.82, 0.98]
Gerstl 2009	167	44	2	130	0.99 [0.96, 1.00]	0.75 [0.68, 0.81]



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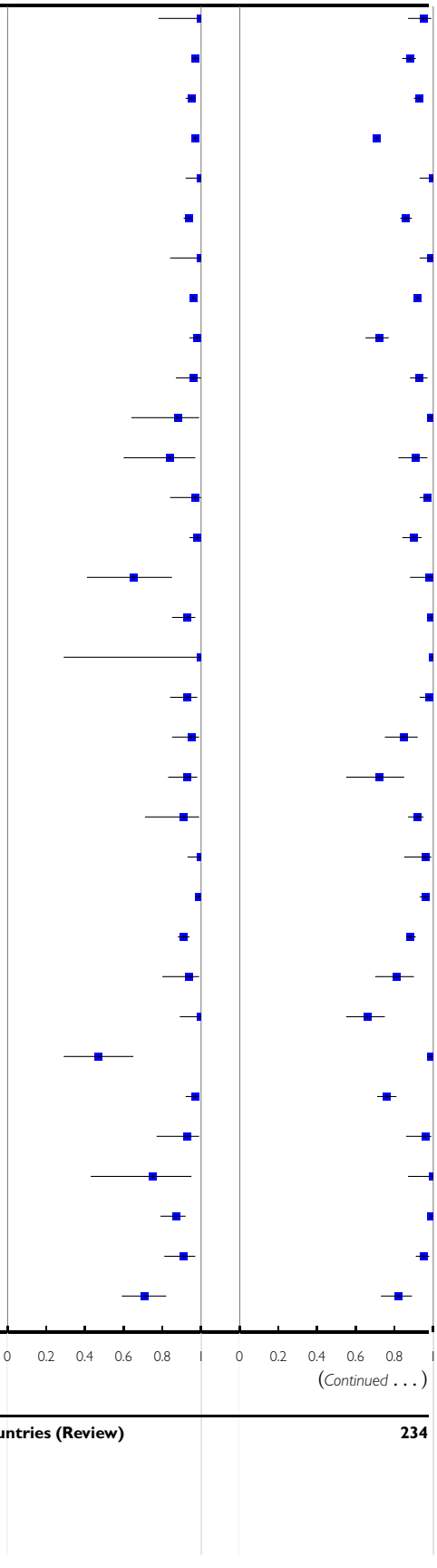
Study	TP	FP	FN	TN	Sensitivity	Specificity
Ghosh 2000	15	3	0	63	1.00 [0.78, 1.00]	0.95 [0.87, 0.99]
Guthmann 2002	412	38	11	280	0.97 [0.95, 0.99]	0.88 [0.84, 0.91]
Hopkins 2007	274	47	15	582	0.95 [0.92, 0.97]	0.93 [0.90, 0.94]
Hopkins 2008a	2626	1245	77	3052	0.97 [0.96, 0.98]	0.71 [0.70, 0.72]
Kar 1998	45	0	0	48	1.00 [0.92, 1.00]	1.00 [0.93, 1.00]
Kilian 1999	635	89	44	558	0.94 [0.91, 0.95]	0.86 [0.83, 0.89]
Kumar 1996	21	1	0	76	1.00 [0.84, 1.00]	0.99 [0.93, 1.00]
Kumar 2004	833	165	34	1859	0.96 [0.95, 0.97]	0.92 [0.91, 0.93]
Kyabayinze 2008	136	62	3	156	0.98 [0.94, 1.00]	0.72 [0.65, 0.77]
Labbe 2001	51	10	2	133	0.96 [0.87, 1.00]	0.93 [0.88, 0.97]
Mboera 2006a	15	4	2	287	0.88 [0.64, 0.99]	0.99 [0.97, 1.00]
Mboera 2006b	16	6	3	63	0.84 [0.60, 0.97]	0.91 [0.82, 0.97]
Mboera 2006c	31	6	1	190	0.97 [0.84, 1.00]	0.97 [0.93, 0.99]
Mboera 2006d	147	16	3	140	0.98 [0.94, 1.00]	0.90 [0.84, 0.94]
Mboera 2006e	13	1	7	43	0.65 [0.41, 0.85]	0.98 [0.88, 1.00]
Mendiratta 2006	75	5	6	357	0.93 [0.85, 0.97]	0.99 [0.97, 1.00]
Mens 2007a	3	0	0	151	1.00 [0.29, 1.00]	1.00 [0.98, 1.00]
Mens 2007b	56	3	4	121	0.93 [0.84, 0.98]	0.98 [0.93, 0.99]
Mharakurwa 1997a	54	12	3	67	0.95 [0.85, 0.99]	0.85 [0.75, 0.92]
Mharakurwa 1997b	53	11	4	28	0.93 [0.83, 0.98]	0.72 [0.55, 0.85]
Mharakurwa 1997c	20	16	2	175	0.91 [0.71, 0.99]	0.92 [0.87, 0.95]
Mohapatra 1996	53	2	0	45	1.00 [0.93, 1.00]	0.96 [0.85, 0.99]
Moonasar 2009	190	8	1	206	0.99 [0.97, 1.00]	0.96 [0.93, 0.98]
Msellem 2009	279	82	26	618	0.91 [0.88, 0.94]	0.88 [0.86, 0.91]
Murahwa 1999	31	12	2	52	0.94 [0.80, 0.99]	0.81 [0.70, 0.90]
Mwanza 2005	32	30	0	57	1.00 [0.89, 1.00]	0.66 [0.55, 0.75]
Nicastri 2009a	15	3	17	301	0.47 [0.29, 0.65]	0.99 [0.97, 1.00]
Nigussie 2008a	147	72	5	228	0.97 [0.92, 0.99]	0.76 [0.71, 0.81]
Nwuba 2001	27	2	2	46	0.93 [0.77, 0.99]	0.96 [0.86, 0.99]
Omar 1999	9	0	3	26	0.75 [0.43, 0.95]	1.00 [0.87, 1.00]
Pandya 2001	98	2	15	352	0.87 [0.79, 0.92]	0.99 [0.98, 1.00]
Pattanasin 2003	52	10	5	202	0.91 [0.81, 0.97]	0.95 [0.91, 0.98]
Sayang 2009	45	16	18	74	0.71 [0.59, 0.82]	0.82 [0.73, 0.89]



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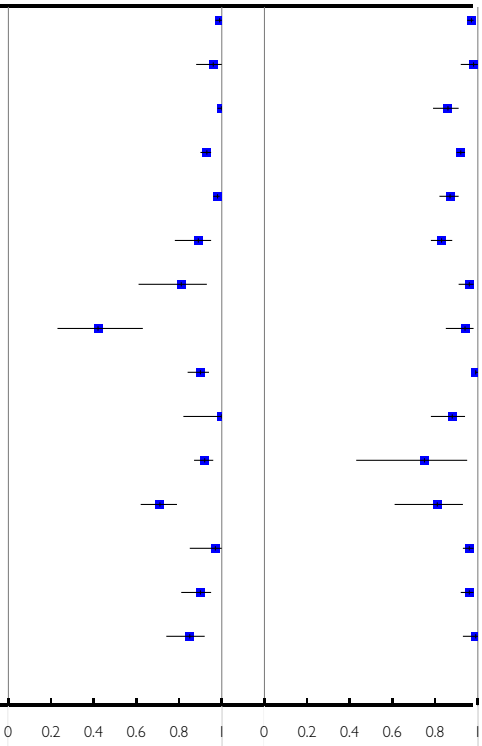
Study	TP	FP	FN	TN	Sensitivity	Specificity
Sharew 2009	167	16	1	484	0.99 [0.97, 1.00]	0.97 [0.95, 0.98]
Sharma 1999	54	1	2	63	0.96 [0.88, 1.00]	0.98 [0.92, 1.00]
Singh 1997 (a)	201	22	0	130	1.00 [0.98, 1.00]	0.86 [0.79, 0.91]
Singh 1997 (b)	354	64	28	785	0.93 [0.90, 0.95]	0.92 [0.90, 0.94]
Singh 2000 (a)	257	35	5	229	0.98 [0.96, 0.99]	0.87 [0.82, 0.91]
Stephens 1999	55	39	7	195	0.89 [0.78, 0.95]	0.83 [0.78, 0.88]
Stow 1999	21	6	5	132	0.81 [0.61, 0.93]	0.96 [0.91, 0.98]
Tagbo 2007	11	4	15	59	0.42 [0.23, 0.63]	0.94 [0.85, 0.98]
Van den Broek 2006	137	4	15	740	0.90 [0.84, 0.94]	0.99 [0.99, 1.00]
Verle 1996	19	9	0	65	1.00 [0.82, 1.00]	0.88 [0.78, 0.94]
Willcox 2009a	135	3	11	9	0.92 [0.87, 0.96]	0.75 [0.43, 0.95]
Willcox 2009b	83	5	34	21	0.71 [0.62, 0.79]	0.81 [0.61, 0.93]
Wolday 2001	35	11	1	259	0.97 [0.85, 1.00]	0.96 [0.93, 0.98]
Wongsrichanalai 1999	69	10	8	222	0.90 [0.81, 0.95]	0.96 [0.92, 0.98]
Yadav 1997	60	1	11	76	0.85 [0.74, 0.92]	0.99 [0.93, 1.00]

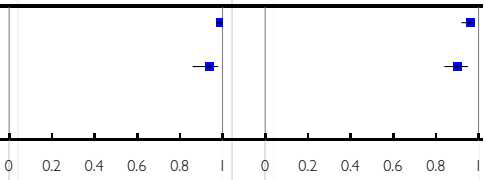


Test 12. CareStart Malaria Pf/Pan.

Review: Rapid diagnostic tests for diagnosing uncomplicated *P. falciparum* malaria in endemic countries

Test: 12 CareStart Malaria Pf/Pan

Study	TP	FP	FN	TN	Sensitivity	Specificity
Gerstl 2009	168	7	1	167	0.99 [0.97, 1.00]	0.96 [0.92, 0.98]
Ratsimbasoa 2007	67	12	4	111	0.94 [0.86, 0.98]	0.90 [0.84, 0.95]

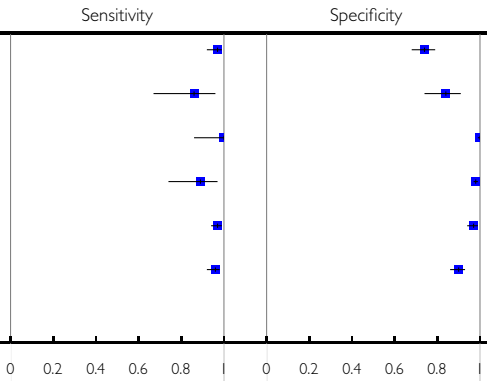


Test 13. ICT Malaria Pf/Pv.

Review: Rapid diagnostic tests for diagnosing uncomplicated *P. falciparum* malaria in endemic countries

Test: 13 ICT Malaria Pf/Pv

Study	TP	FP	FN	TN	Sensitivity	Specificity
Bell 2001a	103	64	3	180	0.97 [0.92, 0.99]	0.74 [0.68, 0.79]
Bell 2001b	24	14	4	71	0.86 [0.67, 0.96]	0.84 [0.74, 0.91]
Fernando 2004	24	0	0	304	1.00 [0.86, 1.00]	1.00 [0.99, 1.00]
Harani 2006	32	9	4	515	0.89 [0.74, 0.97]	0.98 [0.97, 0.99]
Singh 2000 (c)	155	5	4	180	0.97 [0.94, 0.99]	0.97 [0.94, 0.99]
Tjitra 1999	236	32	11	281	0.96 [0.92, 0.98]	0.90 [0.86, 0.93]

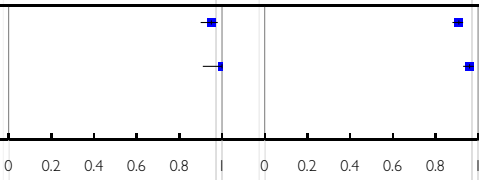


Test 14. NOW malaria ICT.

Review: Rapid diagnostic tests for diagnosing uncomplicated *P. falciparum* malaria in endemic countries

Test: 14 NOW malaria ICT

Study	TP	FP	FN	TN	Sensitivity	Specificity
Van den Broek 2006	144	70	8	674	0.95 [0.90, 0.98]	0.91 [0.88, 0.93]
Wongsrichanalai 2003	38	8	0	200	1.00 [0.91, 1.00]	0.96 [0.93, 0.98]

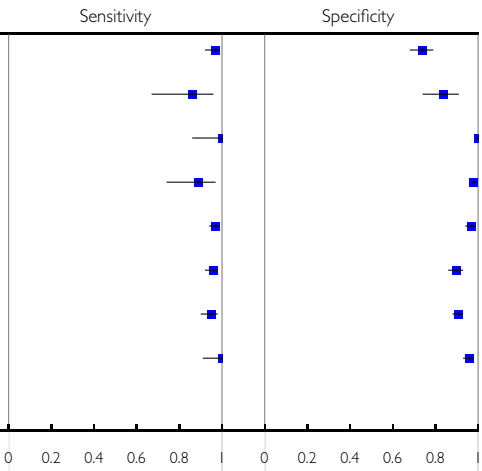


Test 15. Type 2 (All).

Review: Rapid diagnostic tests for diagnosing uncomplicated *P. falciparum* malaria in endemic countries

Test: 15 Type 2 (All)

Study	TP	FP	FN	TN	Sensitivity	Specificity
Bell 2001a	103	64	3	180	0.97 [0.92, 0.99]	0.74 [0.68, 0.79]
Bell 2001b	24	14	4	71	0.86 [0.67, 0.96]	0.84 [0.74, 0.91]
Fernando 2004	24	0	0	304	1.00 [0.86, 1.00]	1.00 [0.99, 1.00]
Harani 2006	32	9	4	515	0.89 [0.74, 0.97]	0.98 [0.97, 0.99]
Singh 2000 (c)	155	5	4	180	0.97 [0.94, 0.99]	0.97 [0.94, 0.99]
Tjitra 1999	236	32	11	281	0.96 [0.92, 0.98]	0.90 [0.86, 0.93]
Van den Broek 2006	144	70	8	674	0.95 [0.90, 0.98]	0.91 [0.88, 0.93]
Wongsrichanalai 2003	38	8	0	200	1.00 [0.91, 1.00]	0.96 [0.93, 0.98]

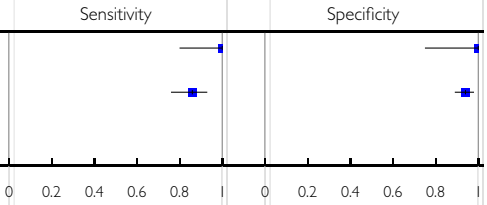


Test 16. SD Malaria Antigen Bioline.

Review: Rapid diagnostic tests for diagnosing uncomplicated *P. falciparum* malaria in endemic countries

Test: 16 SD Malaria Antigen Bioline

Study	TP	FP	FN	TN	Sensitivity	Specificity
Dev 2004	17	0	0	13	1.00 [0.80, 1.00]	1.00 [0.75, 1.00]
Ratsimbasoa 2007	61	7	10	116	0.86 [0.76, 0.93]	0.94 [0.89, 0.98]

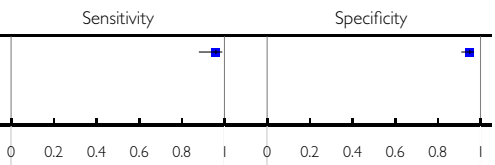


Test 17. First Response Malaria.

Review: Rapid diagnostic tests for diagnosing uncomplicated *P. falciparum* malaria in endemic countries

Test: 17 First Response Malaria

Study	TP	FP	FN	TN	Sensitivity	Specificity
Bharti 2008	69	12	3	207	0.96 [0.88, 0.99]	0.95 [0.91, 0.97]

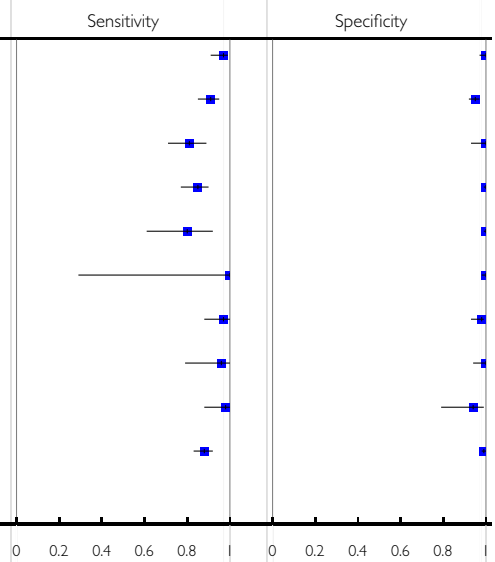


Test 18. OptiMAL/ OptiMAL 48.

Review: Rapid diagnostic tests for diagnosing uncomplicated *P. falciparum* malaria in endemic countries

Test: 18 OptiMAL/ OptiMAL 48

Study	TP	FP	FN	TN	Sensitivity	Specificity
Chayani 2004	93	0	3	136	0.97 [0.91, 0.99]	1.00 [0.97, 1.00]
Cooke 1999	131	13	13	244	0.91 [0.85, 0.95]	0.95 [0.92, 0.97]
Dev 2004	69	0	16	54	0.81 [0.71, 0.89]	1.00 [0.93, 1.00]
Iqbal 2003	111	3	20	796	0.85 [0.77, 0.90]	1.00 [0.99, 1.00]
Kolaczinski 2004	24	1	6	468	0.80 [0.61, 0.92]	1.00 [0.99, 1.00]
Mens 2007a	3	0	0	151	1.00 [0.29, 1.00]	1.00 [0.98, 1.00]
Mens 2007b	58	3	2	121	0.97 [0.88, 1.00]	0.98 [0.93, 0.99]
Singh 2003a	23	0	1	56	0.96 [0.79, 1.00]	1.00 [0.94, 1.00]
Singh 2003b	43	2	1	29	0.98 [0.88, 1.00]	0.94 [0.79, 0.99]
Valecha 2003	190	5	26	478	0.88 [0.83, 0.92]	0.99 [0.98, 1.00]

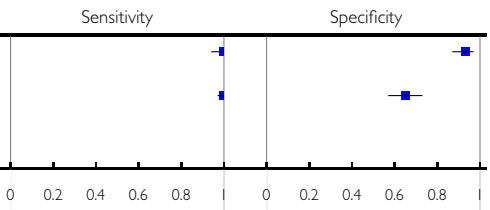


Test 19. Parascreen.

Review: Rapid diagnostic tests for diagnosing uncomplicated *P. falciparum* malaria in endemic countries

Test: 19 Parascreen

Study	TP	FP	FN	TN	Sensitivity	Specificity
Mens 2007b	60	9	0	115	1.00 [0.94, 1.00]	0.93 [0.87, 0.97]
Nigussie 2008b	110	52	0	97	1.00 [0.97, 1.00]	0.65 [0.57, 0.73]

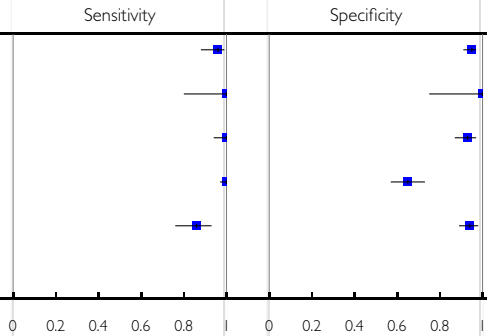


Test 20. Type 3 (All).

Review: Rapid diagnostic tests for diagnosing uncomplicated *P. falciparum* malaria in endemic countries

Test: 20 Type 3 (All)

Study	TP	FP	FN	TN	Sensitivity	Specificity
Bharti 2008	69	12	3	207	0.96 [0.88, 0.99]	0.95 [0.91, 0.97]
Dev 2004	17	0	0	13	1.00 [0.80, 1.00]	1.00 [0.75, 1.00]
Mens 2007b	60	9	0	115	1.00 [0.94, 1.00]	0.93 [0.87, 0.97]
Nigussie 2008b	110	52	0	97	1.00 [0.97, 1.00]	0.65 [0.57, 0.73]
Ratsimbasoa 2007	61	7	10	116	0.86 [0.76, 0.93]	0.94 [0.89, 0.98]

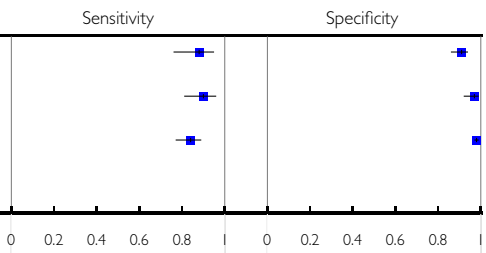


Test 21. OptiMAL-IT.

Review: Rapid diagnostic tests for diagnosing uncomplicated *P. falciparum* malaria in endemic countries

Test: 21 OptiMAL-IT

Study	TP	FP	FN	TN	Sensitivity	Specificity
Pattanasin 2003	50	19	7	190	0.88 [0.76, 0.95]	0.91 [0.86, 0.94]
Ratsimbasoa 2007	64	4	7	119	0.90 [0.81, 0.96]	0.97 [0.92, 0.99]
Van den Broek 2006	127	13	25	731	0.84 [0.77, 0.89]	0.98 [0.97, 0.99]

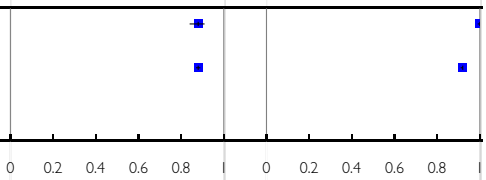


Test 22. Parabank.

Review: Rapid diagnostic tests for diagnosing uncomplicated *P. falciparum* malaria in endemic countries

Test: 22 Parabank

Study	TP	FP	FN	TN	Sensitivity	Specificity
Hopkins 2007	254	0	35	629	0.88 [0.84, 0.91]	1.00 [0.99, 1.00]
Hopkins 2008a	2385	358	318	3939	0.88 [0.87, 0.89]	0.92 [0.91, 0.92]

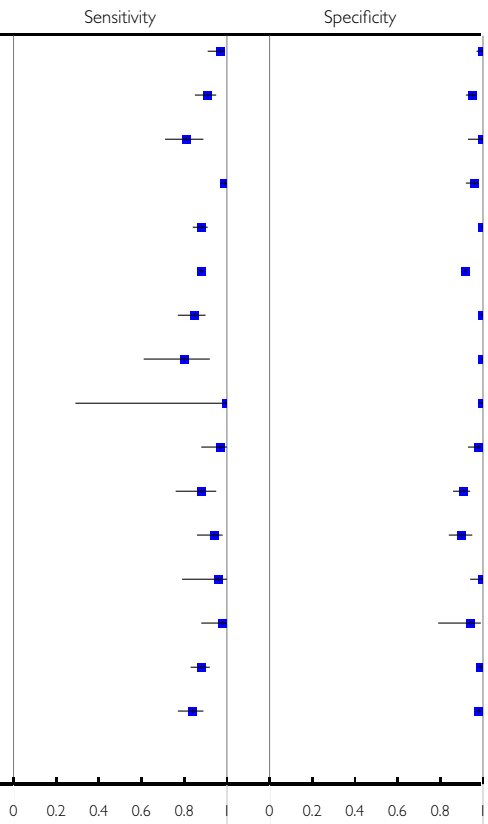


Test 23. Type 4 (All).

Review: Rapid diagnostic tests for diagnosing uncomplicated *P. falciparum* malaria in endemic countries

Test: 23 Type 4 (All)

Study	TP	FP	FN	TN	Sensitivity	Specificity
Chayani 2004	93	0	3	136	0.97 [0.91, 0.99]	1.00 [0.97, 1.00]
Cooke 1999	131	13	13	244	0.91 [0.85, 0.95]	0.95 [0.92, 0.97]
Dev 2004	69	0	16	54	0.81 [0.71, 0.89]	1.00 [0.93, 1.00]
Gerstl 2009	168	7	1	167	0.99 [0.97, 1.00]	0.96 [0.92, 0.98]
Hopkins 2007	254	0	35	629	0.88 [0.84, 0.91]	1.00 [0.99, 1.00]
Hopkins 2008a	2385	358	318	3939	0.88 [0.87, 0.89]	0.92 [0.91, 0.92]
Iqbal 2003	111	3	20	796	0.85 [0.77, 0.90]	1.00 [0.99, 1.00]
Kolaczinski 2004	24	1	6	468	0.80 [0.61, 0.92]	1.00 [0.99, 1.00]
Mens 2007a	3	0	0	151	1.00 [0.29, 1.00]	1.00 [0.98, 1.00]
Mens 2007b	58	3	2	121	0.97 [0.88, 1.00]	0.98 [0.93, 0.99]
Pattanasin 2003	50	19	7	190	0.88 [0.76, 0.95]	0.91 [0.86, 0.94]
Ratsimbasoa 2007	67	12	4	111	0.94 [0.86, 0.98]	0.90 [0.84, 0.95]
Singh 2003a	23	0	1	56	0.96 [0.79, 1.00]	1.00 [0.94, 1.00]
Singh 2003b	43	2	1	29	0.98 [0.88, 1.00]	0.94 [0.79, 0.99]
Valecha 2003	190	5	26	478	0.88 [0.83, 0.92]	0.99 [0.98, 1.00]
Van den Broek 2006	127	13	25	731	0.84 [0.77, 0.89]	0.98 [0.97, 0.99]

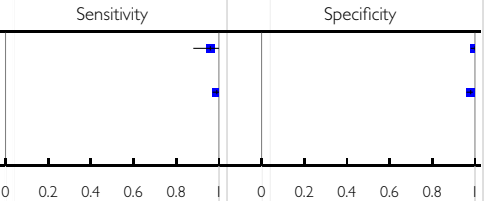


Test 24. Carestart Pf/Pv.

Review: Rapid diagnostic tests for diagnosing uncomplicated *P. falciparum* malaria in endemic countries

Test: 24 Carestart Pf/Pv

Study	TP	FP	FN	TN	Sensitivity	Specificity
Mekonnen 2010	54	0	2	184	0.96 [0.88, 1.00]	1.00 [0.98, 1.00]
Sharew 2009	167	10	1	490	0.99 [0.97, 1.00]	0.98 [0.96, 0.99]

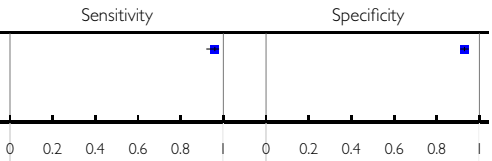


Test 25. ParaSight Pf/Pv.

Review: Rapid diagnostic tests for diagnosing uncomplicated *P. falciparum* malaria in endemic countries

Test: 25 ParaSight Pf/Pv

Study	TP	FP	FN	TN	Sensitivity	Specificity
Forney 2003	169	46	7	647	0.96 [0.92, 0.98]	0.93 [0.91, 0.95]

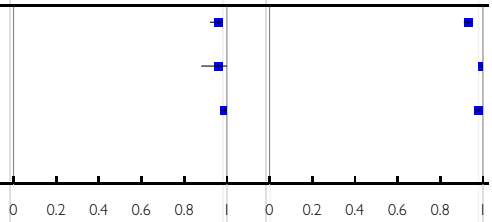


Test 26. Type 5 (All).

Review: Rapid diagnostic tests for diagnosing uncomplicated *P. falciparum* malaria in endemic countries

Test: 26 Type 5 (All)

Study	TP	FP	FN	TN	Sensitivity	Specificity
Forney 2003	169	46	7	647	0.96 [0.92, 0.98]	0.93 [0.91, 0.95]
Mekonnen 2010	54	0	2	184	0.96 [0.88, 1.00]	1.00 [0.98, 1.00]
Sharew 2009	167	10	1	490	0.99 [0.97, 1.00]	0.98 [0.96, 0.99]

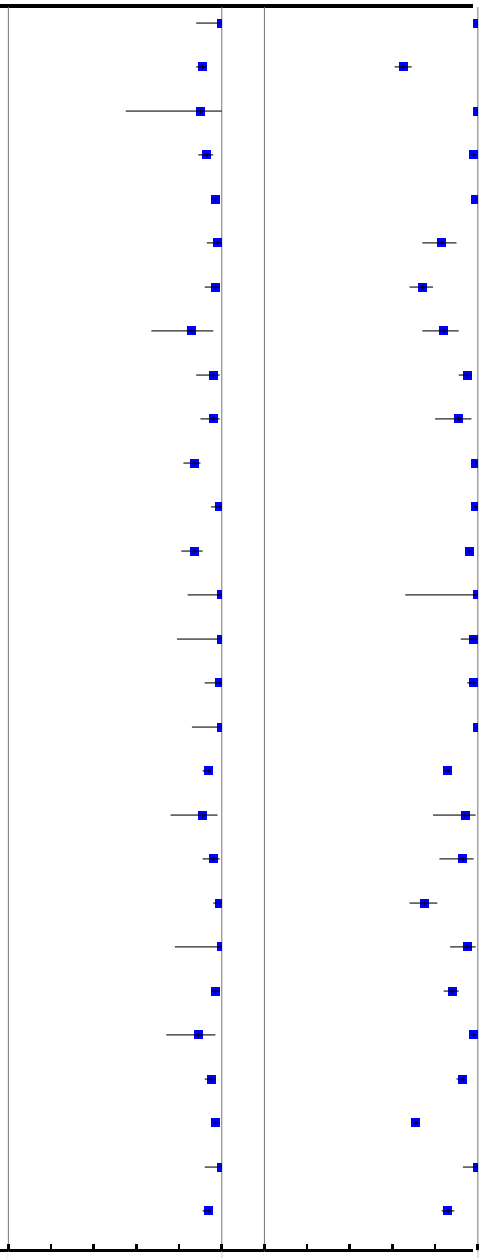


Test 27. HRP-2 based tests.

Review: Rapid diagnostic tests for diagnosing uncomplicated *P. falciparum* malaria in endemic countries

Test: 27 HRP-2 based tests

Study	TP	FP	FN	TN	Sensitivity	Specificity
A-Elgayoum 2009	28	0	0	382	1.00 [0.88, 1.00]	1.00 [0.99, 1.00]
Abeku 2008a	554	220	55	408	0.91 [0.88, 0.93]	0.65 [0.61, 0.69]
Abeku 2008b	9	1	1	989	0.90 [0.55, 1.00]	1.00 [0.99, 1.00]
Banchongaksorn 1996a	226	12	16	659	0.93 [0.89, 0.96]	0.98 [0.97, 0.99]
Banchongaksorn 1997	598	20	21	2722	0.97 [0.95, 0.98]	0.99 [0.99, 1.00]
Bechem 1999	98	17	2	82	0.98 [0.93, 1.00]	0.83 [0.74, 0.90]
Bell 2001a	103	64	3	180	0.97 [0.92, 0.99]	0.74 [0.68, 0.79]
Bell 2001b	24	14	4	71	0.86 [0.67, 0.96]	0.84 [0.74, 0.91]
Bharti 2008	69	12	3	207	0.96 [0.88, 0.99]	0.95 [0.91, 0.97]
Bojang 1999	82	5	3	49	0.96 [0.90, 0.99]	0.91 [0.80, 0.97]
Caraballo 1996	268	8	41	1081	0.87 [0.82, 0.90]	0.99 [0.99, 1.00]
Chitkara 2004	135	5	2	531	0.99 [0.95, 1.00]	0.99 [0.98, 1.00]
De Oliveira 2009	163	65	25	1574	0.87 [0.81, 0.91]	0.96 [0.95, 0.97]
Dev 2004	21	0	0	9	1.00 [0.84, 1.00]	1.00 [0.66, 1.00]
Devi 2002	16	2	0	82	1.00 [0.79, 1.00]	0.98 [0.92, 1.00]
Durrheim 1998	68	4	1	191	0.99 [0.92, 1.00]	0.98 [0.95, 0.99]
Fernando 2004	24	0	0	304	1.00 [0.86, 1.00]	1.00 [0.99, 1.00]
Forney 2001	541	346	37	2057	0.94 [0.91, 0.95]	0.86 [0.84, 0.87]
Gaye 1998	31	2	3	30	0.91 [0.76, 0.98]	0.94 [0.79, 0.99]
Gaye 1999	122	4	5	51	0.96 [0.91, 0.99]	0.93 [0.82, 0.98]
Gerstl 2009	167	44	2	130	0.99 [0.96, 1.00]	0.75 [0.68, 0.81]
Ghosh 2000	15	3	0	63	1.00 [0.78, 1.00]	0.95 [0.87, 0.99]
Guthmann 2002	412	38	11	280	0.97 [0.95, 0.99]	0.88 [0.84, 0.91]
Harani 2006	32	9	4	515	0.89 [0.74, 0.97]	0.98 [0.97, 0.99]
Hopkins 2007	274	47	15	582	0.95 [0.92, 0.97]	0.93 [0.90, 0.94]
Hopkins 2008a	2626	1245	77	3052	0.97 [0.96, 0.98]	0.71 [0.70, 0.72]
Kar 1998	45	0	0	48	1.00 [0.92, 1.00]	1.00 [0.93, 1.00]
Kilian 1999	635	89	44	558	0.94 [0.91, 0.95]	0.86 [0.83, 0.89]



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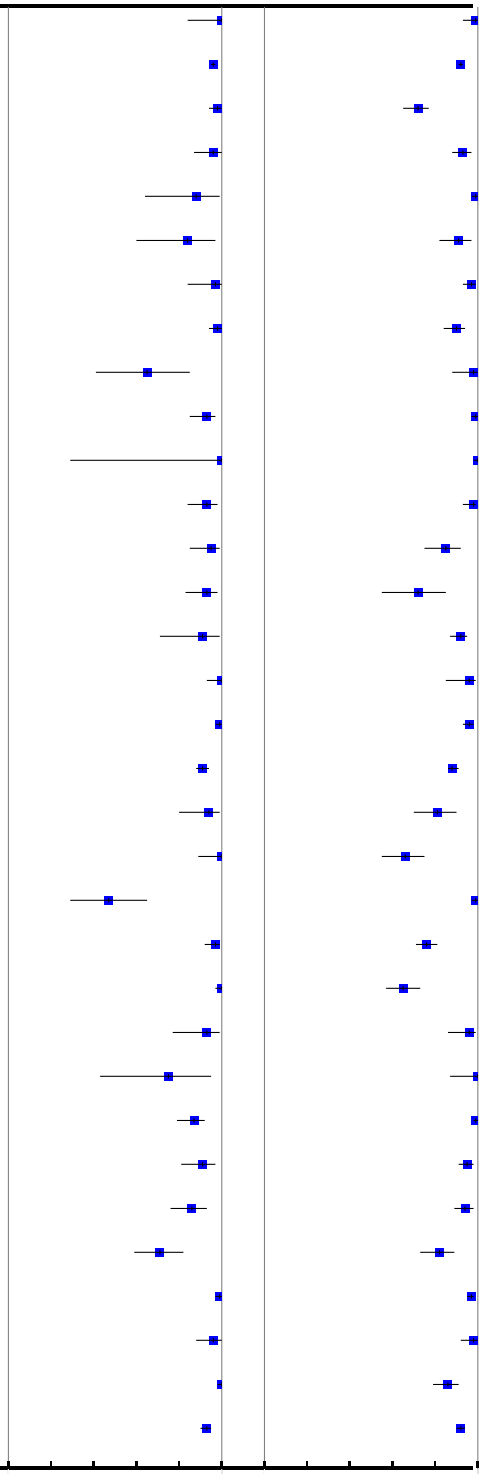
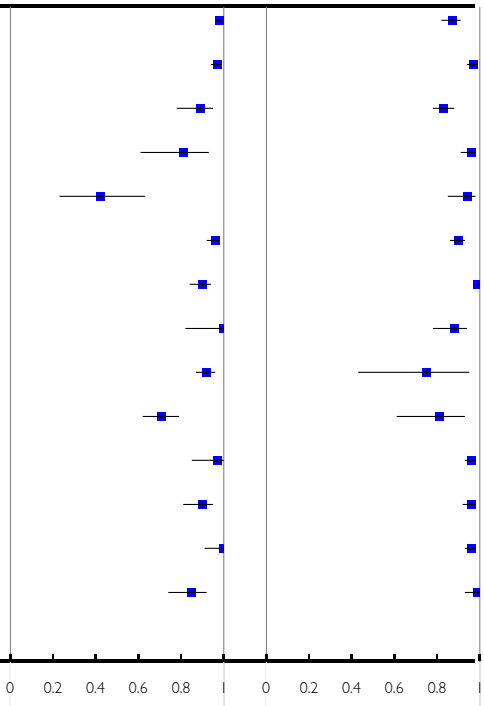
Study	TP	FP	FN	TN	Sensitivity	Specificity
Kumar 1996	21	1	0	76	1.00 [0.84, 1.00]	0.99 [0.93, 1.00]
Kumar 2004	833	165	34	1859	0.96 [0.95, 0.97]	0.92 [0.91, 0.93]
Kyabayinze 2008	136	62	3	156	0.98 [0.94, 1.00]	0.72 [0.65, 0.77]
Labbe 2001	51	10	2	133	0.96 [0.87, 1.00]	0.93 [0.88, 0.97]
Mboera 2006a	15	4	2	287	0.88 [0.64, 0.99]	0.99 [0.97, 1.00]
Mboera 2006b	16	6	3	63	0.84 [0.60, 0.97]	0.91 [0.82, 0.97]
Mboera 2006c	31	6	1	190	0.97 [0.84, 1.00]	0.97 [0.93, 0.99]
Mboera 2006d	147	16	3	140	0.98 [0.94, 1.00]	0.90 [0.84, 0.94]
Mboera 2006e	13	1	7	43	0.65 [0.41, 0.85]	0.98 [0.88, 1.00]
Mendiratta 2006	75	5	6	357	0.93 [0.85, 0.97]	0.99 [0.97, 1.00]
Mens 2007a	3	0	0	151	1.00 [0.29, 1.00]	1.00 [0.98, 1.00]
Mens 2007b	56	3	4	121	0.93 [0.84, 0.98]	0.98 [0.93, 0.99]
Mharakurwa 1997a	54	12	3	67	0.95 [0.85, 0.99]	0.85 [0.75, 0.92]
Mharakurwa 1997b	53	11	4	28	0.93 [0.83, 0.98]	0.72 [0.55, 0.85]
Mharakurwa 1997c	20	16	2	175	0.91 [0.71, 0.99]	0.92 [0.87, 0.95]
Mohapatra 1996	53	2	0	45	1.00 [0.93, 1.00]	0.96 [0.85, 0.99]
Moonasar 2009	190	8	1	206	0.99 [0.97, 1.00]	0.96 [0.93, 0.98]
Msellem 2009	279	82	26	618	0.91 [0.88, 0.94]	0.88 [0.86, 0.91]
Murahwa 1999	31	12	2	52	0.94 [0.80, 0.99]	0.81 [0.70, 0.90]
Mwanza 2005	32	30	0	57	1.00 [0.89, 1.00]	0.66 [0.55, 0.75]
Nicastri 2009a	15	3	17	301	0.47 [0.29, 0.65]	0.99 [0.97, 1.00]
Nigussie 2008a	147	72	5	228	0.97 [0.92, 0.99]	0.76 [0.71, 0.81]
Nigussie 2008b	110	52	0	97	1.00 [0.97, 1.00]	0.65 [0.57, 0.73]
Nwuba 2001	27	2	2	46	0.93 [0.77, 0.99]	0.96 [0.86, 0.99]
Omar 1999	9	0	3	26	0.75 [0.43, 0.95]	1.00 [0.87, 1.00]
Pandya 2001	98	2	15	352	0.87 [0.79, 0.92]	0.99 [0.98, 1.00]
Pattanasin 2003	52	10	5	202	0.91 [0.81, 0.97]	0.95 [0.91, 0.98]
Ratsimbasoa 2007	61	7	10	116	0.86 [0.76, 0.93]	0.94 [0.89, 0.98]
Sayang 2009	45	16	18	74	0.71 [0.59, 0.82]	0.82 [0.73, 0.89]
Sharew 2009	167	16	1	484	0.99 [0.97, 1.00]	0.97 [0.95, 0.98]
Sharma 1999	54	1	2	63	0.96 [0.88, 1.00]	0.98 [0.92, 1.00]
Singh 1997 (a)	201	22	0	130	1.00 [0.98, 1.00]	0.86 [0.79, 0.91]
Singh 1997 (b)	354	64	28	785	0.93 [0.90, 0.95]	0.92 [0.90, 0.94]



(*Continued* . . .)

(. . . *Continued*)

Study	TP	FP	FN	TN	Sensitivity	Specificity
Singh 2000 (a)	257	35	5	229	0.98 [0.96, 0.99]	0.87 [0.82, 0.91]
Singh 2000 (c)	155	5	4	180	0.97 [0.94, 0.99]	0.97 [0.94, 0.99]
Stephens 1999	55	39	7	195	0.89 [0.78, 0.95]	0.83 [0.78, 0.88]
Stow 1999	21	6	5	132	0.81 [0.61, 0.93]	0.96 [0.91, 0.98]
Tagbo 2007	11	4	15	59	0.42 [0.23, 0.63]	0.94 [0.85, 0.98]
Tjitra 1999	236	32	11	281	0.96 [0.92, 0.98]	0.90 [0.86, 0.93]
Van den Broek 2006	137	4	15	740	0.90 [0.84, 0.94]	0.99 [0.99, 1.00]
Verle 1996	19	9	0	65	1.00 [0.82, 1.00]	0.88 [0.78, 0.94]
Willcox 2009a	135	3	11	9	0.92 [0.87, 0.96]	0.75 [0.43, 0.95]
Willcox 2009b	83	5	34	21	0.71 [0.62, 0.79]	0.81 [0.61, 0.93]
Wolday 2001	35	11	1	259	0.97 [0.85, 1.00]	0.96 [0.93, 0.98]
Wongsrichanalai 1999	69	10	8	222	0.90 [0.81, 0.95]	0.96 [0.92, 0.98]
Wongsrichanalai 2003	38	8	0	200	1.00 [0.91, 1.00]	0.96 [0.93, 0.98]
Yadav 1997	60	1	11	76	0.85 [0.74, 0.92]	0.99 [0.93, 1.00]

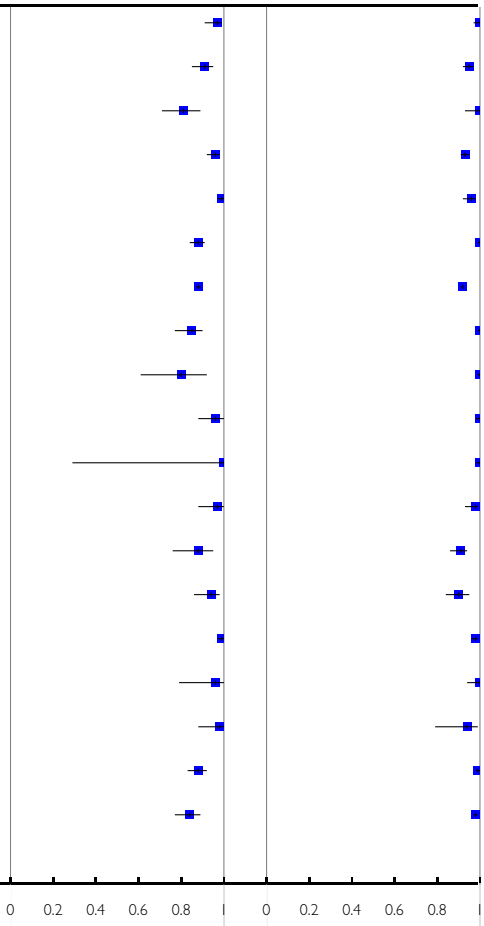


Test 28. pLDH based tests.

Review: Rapid diagnostic tests for diagnosing uncomplicated *P. falciparum* malaria in endemic countries

Test: 28 pLDH based tests

Study	TP	FP	FN	TN	Sensitivity	Specificity
Chayani 2004	93	0	3	136	0.97 [0.91, 0.99]	1.00 [0.97, 1.00]
Cooke 1999	131	13	13	244	0.91 [0.85, 0.95]	0.95 [0.92, 0.97]
Dev 2004	69	0	16	54	0.81 [0.71, 0.89]	1.00 [0.93, 1.00]
Forney 2003	169	46	7	647	0.96 [0.92, 0.98]	0.93 [0.91, 0.95]
Gerstl 2009	168	7	1	167	0.99 [0.97, 1.00]	0.96 [0.92, 0.98]
Hopkins 2007	254	0	35	629	0.88 [0.84, 0.91]	1.00 [0.99, 1.00]
Hopkins 2008a	2385	358	318	3939	0.88 [0.87, 0.89]	0.92 [0.91, 0.92]
Iqbal 2003	111	3	20	796	0.85 [0.77, 0.90]	1.00 [0.99, 1.00]
Kolaczinski 2004	24	1	6	468	0.80 [0.61, 0.92]	1.00 [0.99, 1.00]
Mekonnen 2010	54	0	2	184	0.96 [0.88, 1.00]	1.00 [0.98, 1.00]
Mens 2007a	3	0	0	151	1.00 [0.29, 1.00]	1.00 [0.98, 1.00]
Mens 2007b	58	3	2	121	0.97 [0.88, 1.00]	0.98 [0.93, 0.99]
Pattanasin 2003	50	19	7	190	0.88 [0.76, 0.95]	0.91 [0.86, 0.94]
Ratsimbasoa 2007	67	12	4	111	0.94 [0.86, 0.98]	0.90 [0.84, 0.95]
Sharew 2009	167	10	1	490	0.99 [0.97, 1.00]	0.98 [0.96, 0.99]
Singh 2003a	23	0	1	56	0.96 [0.79, 1.00]	1.00 [0.94, 1.00]
Singh 2003b	43	2	1	29	0.98 [0.88, 1.00]	0.94 [0.79, 0.99]
Valecha 2003	190	5	26	478	0.88 [0.83, 0.92]	0.99 [0.98, 1.00]
Van den Broek 2006	127	13	25	731	0.84 [0.77, 0.89]	0.98 [0.97, 0.99]

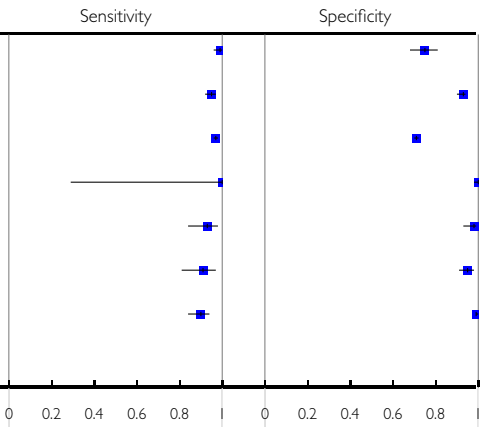


Test 29. Type 1 (paired comparison with Type 4).

Review: Rapid diagnostic tests for diagnosing uncomplicated *P. falciparum* malaria in endemic countries

Test: 29 Type 1 (paired comparison with Type 4)

Study	TP	FP	FN	TN	Sensitivity	Specificity
Gerstl 2009	167	44	2	130	0.99 [0.96, 1.00]	0.75 [0.68, 0.81]
Hopkins 2007	274	47	15	582	0.95 [0.92, 0.97]	0.93 [0.90, 0.94]
Hopkins 2008a	2626	1245	77	3052	0.97 [0.96, 0.98]	0.71 [0.70, 0.72]
Mens 2007a	3	0	0	151	1.00 [0.29, 1.00]	1.00 [0.98, 1.00]
Mens 2007b	56	3	4	121	0.93 [0.84, 0.98]	0.98 [0.93, 0.99]
Pattanasin 2003	52	10	5	202	0.91 [0.81, 0.97]	0.95 [0.91, 0.98]
Van den Broek 2006	137	4	15	740	0.90 [0.84, 0.94]	0.99 [0.99, 1.00]

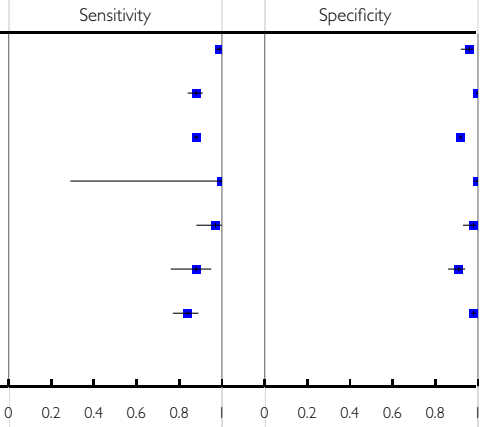


Test 30. Type 4 (paired comparison with Type 1).

Review: Rapid diagnostic tests for diagnosing uncomplicated *P. falciparum* malaria in endemic countries

Test: 30 Type 4 (paired comparison with Type 1)

Study	TP	FP	FN	TN	Sensitivity	Specificity
Gerstl 2009	168	7	1	167	0.99 [0.97, 1.00]	0.96 [0.92, 0.98]
Hopkins 2007	254	0	35	629	0.88 [0.84, 0.91]	1.00 [0.99, 1.00]
Hopkins 2008a	2385	358	318	3939	0.88 [0.87, 0.89]	0.92 [0.91, 0.92]
Mens 2007a	3	0	0	151	1.00 [0.29, 1.00]	1.00 [0.98, 1.00]
Mens 2007b	58	3	2	121	0.97 [0.88, 1.00]	0.98 [0.93, 0.99]
Pattanasin 2003	50	19	7	190	0.88 [0.76, 0.95]	0.91 [0.86, 0.94]
Van den Broek 2006	127	13	25	731	0.84 [0.77, 0.89]	0.98 [0.97, 0.99]

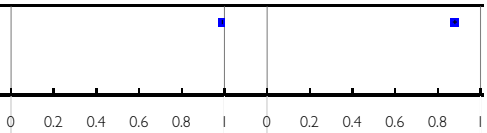


Test 31. PCR adjusted microscopy, Type 1, Paracheck-PF (All).

Review: Rapid diagnostic tests for diagnosing uncomplicated *P. falciparum* malaria in endemic countries

Test: 31 PCR adjusted microscopy, Type 1, Paracheck-PF (All)

Study	TP	FP	FN	TN	Sensitivity	Specificity	Sensitivity	Specificity
Hopkins 2008b	3454	417	34	3095	0.99 [0.99, 0.99]	0.88 [0.87, 0.89]		

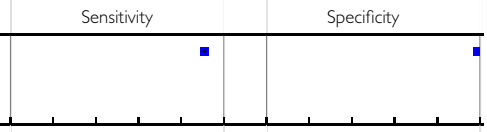


Test 32. PCR adjusted microscopy, Type 4, Parabank (All).

Review: Rapid diagnostic tests for diagnosing uncomplicated *P. falciparum* malaria in endemic countries

Test: 32 PCR adjusted microscopy, Type 4, Parabank (All)

Study	TP	FP	FN	TN	Sensitivity	Specificity	Sensitivity	Specificity
Hopkins 2008b	2707	36	284	3973	0.91 [0.89, 0.92]	0.99 [0.99, 0.99]		

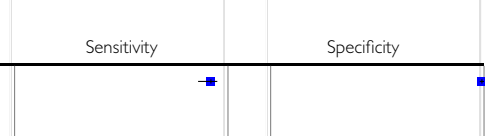


Test 33. PCR, Type 1, ParaSight-F.

Review: Rapid diagnostic tests for diagnosing uncomplicated *P. falciparum* malaria in endemic countries

Test: 33 PCR, Type 1, ParaSight-F

Study	TP	FP	FN	TN	Sensitivity	Specificity	Sensitivity	Specificity
Banchongaksorn 1996b	153	2	14	351	0.92 [0.86, 0.95]	0.99 [0.98, 1.00]		

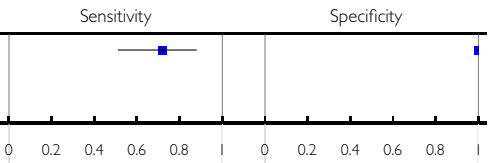


Test 34. PCR, Type 1, ParaHIT-F.

Review: Rapid diagnostic tests for diagnosing uncomplicated *P. falciparum* malaria in endemic countries

Test: 34 PCR, Type 1, ParaHIT-F

Study	TP	FP	FN	TN	Sensitivity	Specificity
Nicastri 2009b	18	0	7	311	0.72 [0.51, 0.88]	1.00 [0.99, 1.00]

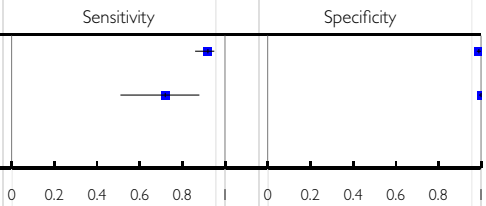


Test 35. PCR, Type 1 (All).

Review: Rapid diagnostic tests for diagnosing uncomplicated *P. falciparum* malaria in endemic countries

Test: 35 PCR, Type 1 (All)

Study	TP	FP	FN	TN	Sensitivity	Specificity
Banchongaksorn 1996b	153	2	14	351	0.92 [0.86, 0.95]	0.99 [0.98, 1.00]
Nicastri 2009b	18	0	7	311	0.72 [0.51, 0.88]	1.00 [0.99, 1.00]

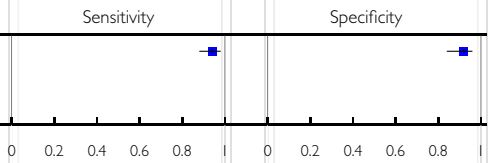


Test 36. PCR, Type 3, SD Malaria Antigen (All).

Review: Rapid diagnostic tests for diagnosing uncomplicated *P. falciparum* malaria in endemic countries

Test: 36 PCR, Type 3, SD Malaria Antigen (All)

Study	TP	FP	FN	TN	Sensitivity	Specificity
Ratsimbasoa 2008	95	8	6	89	0.94 [0.88, 0.98]	0.92 [0.84, 0.96]

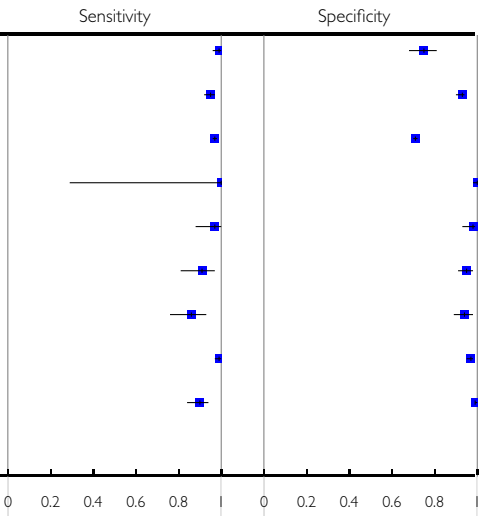


Test 37. HRP-2 based tests paired data.

Review: Rapid diagnostic tests for diagnosing uncomplicated *P. falciparum* malaria in endemic countries

Test: 37 HRP-2 based tests paired data

Study	TP	FP	FN	TN	Sensitivity	Specificity
Gerstl 2009	167	44	2	130	0.99 [0.96, 1.00]	0.75 [0.68, 0.81]
Hopkins 2007	274	47	15	582	0.95 [0.92, 0.97]	0.93 [0.90, 0.94]
Hopkins 2008a	2626	1245	77	3052	0.97 [0.96, 0.98]	0.71 [0.70, 0.72]
Mens 2007a	3	0	0	151	1.00 [0.29, 1.00]	1.00 [0.98, 1.00]
Mens 2007b	58	3	2	121	0.97 [0.88, 1.00]	0.98 [0.93, 0.99]
Pattanasin 2003	52	10	5	202	0.91 [0.81, 0.97]	0.95 [0.91, 0.98]
Ratsimbasoa 2007	61	7	10	116	0.86 [0.76, 0.93]	0.94 [0.89, 0.98]
Sharew 2009	167	16	1	484	0.99 [0.97, 1.00]	0.97 [0.95, 0.98]
Van den Broek 2006	137	4	15	740	0.90 [0.84, 0.94]	0.99 [0.99, 1.00]

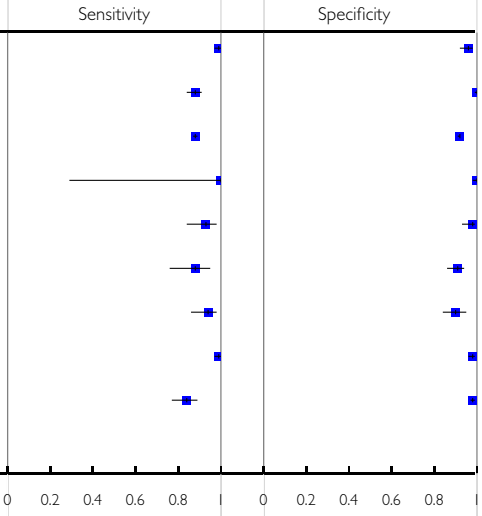


Test 38. pLDH based tests paired data.

Review: Rapid diagnostic tests for diagnosing uncomplicated *P. falciparum* malaria in endemic countries

Test: 38 pLDH based tests paired data

Study	TP	FP	FN	TN	Sensitivity	Specificity
Gerstl 2009	168	7	1	167	0.99 [0.97, 1.00]	0.96 [0.92, 0.98]
Hopkins 2007	254	0	35	629	0.88 [0.84, 0.91]	1.00 [0.99, 1.00]
Hopkins 2008a	2385	358	318	3939	0.88 [0.87, 0.89]	0.92 [0.91, 0.92]
Mens 2007a	3	0	0	151	1.00 [0.29, 1.00]	1.00 [0.98, 1.00]
Mens 2007b	56	3	4	121	0.93 [0.84, 0.98]	0.98 [0.93, 0.99]
Pattanasin 2003	50	19	7	190	0.88 [0.76, 0.95]	0.91 [0.86, 0.94]
Ratsimbasoa 2007	67	12	4	111	0.94 [0.86, 0.98]	0.90 [0.84, 0.95]
Sharew 2009	167	10	1	490	0.99 [0.97, 1.00]	0.98 [0.96, 0.99]
Van den Broek 2006	127	13	25	731	0.84 [0.77, 0.89]	0.98 [0.97, 0.99]

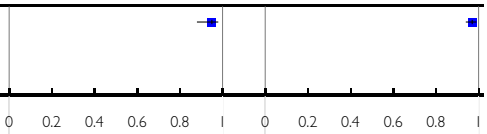


Test 71. PCR, Type 6, PALUTOP (All).

Review: Rapid diagnostic tests for diagnosing uncomplicated *P. falciparum* malaria in endemic countries

Test: 71 PCR, Type 6, PALUTOP (All)

Study	TP	FP	FN	TN	Sensitivity	Specificity	Sensitivity	Specificity
Rakotonirina 2008	86	7	5	215	0.95 [0.88, 0.98]	0.97 [0.94, 0.99]		

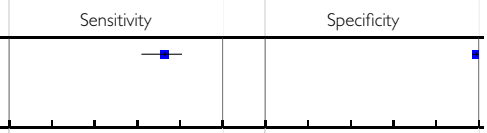


Test 72. PCR, Type 4, OptiMAL-IT (All).

Review: Rapid diagnostic tests for diagnosing uncomplicated *P. falciparum* malaria in endemic countries

Test: 72 PCR, Type 4, OptiMAL-IT (All)

Study	TP	FP	FN	TN	Sensitivity	Specificity	Sensitivity	Specificity
Rakotonirina 2008	66	2	25	220	0.73 [0.62, 0.81]	0.99 [0.97, 1.00]		



APPENDICES

Appendix 1. Appendix 1. Search strategy

Search set	MEDLINE	EMBASE			
1	Exp Malaria[MeSH]	Exp Malaria [Emtree]			
2	Exp Plasmodium [MeSH]	Exp Plasmodium [Emtree]			
3	Malaria ti, ab	Malaria ti, ab			
4	1 or 2 or 3	1 or 2 or 3			
5	Exp Reagent kits, diagnostics [MeSH]	Exp Diagnostic procedures [Emtree]			
6	rapid diagnos* test* ti, ab	rapid diagnos$ test$ ti, ab			
7	RDT ti, ab	RDT ti, ab			
8	Dipstick* ti, ab	Dipstick$ ti, ab			
9	Rapid diagnos* device* ti, ab	Rapid diagnos$ device$ ti, ab			
10	MRDD ti, ab	MRDD ti, ab			
11	OptiMal ti, ab	OptiMal ti, ab			
12	Binax NOW ti, ab	Binax NOW ti, ab			
13	ParaSight ti, ab	ParaSight ti, ab			
14	Immunochromatograph* ti, ab	Immunochromatography [Emtree]			
15	Antigen detection method* ti, ab	Antigen detection method$ ti, ab			
16	Rapid malaria antigen test* ti, ab	Rapid malaria antigen test$ ti, ab			
17	Combo card test* ti, ab	Combo card test$ ti, ab			

(*Continued*)

18	Immunoassay [MeSH]	Immunoassay [Emtree]			
19	Chromatography [MeSH]	Chromatography [Emtree]			
20	Enzyme-linked immunosorbent assay [MeSH]	Enzyme-linked immunosorbent assay [Emtree]			
21	Rapid test* ti, ab	Rapid test$ ti, ab			
22	Card test* ti, ab	Card test$ ti, ab			
23	Rapid AND (detection* or diagnos*) ti, ab	Rapid AND (detection$ or diagnos$) ti, ab			
24	5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23	5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23			
25	4 and 19	4 and 19			
26	Limit 20 to Humans	Limit 20 to Human			
Search set	**Web of Science**	**LILACS**	**Medion**	**African Index medicus**	**IndMed**
1	Malaria (topic)	Malaria	Malaria	Malaria	Malaria
2	Plasmodium falciparum (topic)	Plasmodium falciparum	Diagnos* Or RDT OR (rapid diagnos*)	Plasmodium	Plasmodium
3	1 or 2	1 or 2		1 or 2	1 or 2
4	Rapid diagnostic test* (topic)	Rapid diagnostic test$		Diagnos*	Diagnos*
5	RDT (topic)	RDT		dipstick	dipstick
6	Parasight (topic)	Parasight		combo	combo
7	Immunochromatography (topic)	Immunochromatograp$		Card test	Card test

(*Continued*)

8	Parasight (topic)	Parasight		parasight	parasight
9	Dipstick (topic)	Dipstick		RDT	RDT
10	Binax (topic)	Binax		4 or 5 or 6 or 7 or 8 or 9	4 or 5 or 6 or 7 or 8 or 9
11	4 or 5 or 6 or 7 or 8 or 9 or 10	4 or 5 or 6 or 7 or 8 or 9 or 10		3 and 10	3 and 10
12	3 and 11	3 and 11			

Appendix 2. Data extraction: characteristic of included studies

Study ID	**First author, year of publication**
Clinical features and settings	Presenting signs and symptoms, previous treatments for malaria, clinical setting
Participants	Sample size, age, sex, co-morbidities or pregnancy, country and locality, *P. falciparum* malaria endemicity, endemic malaria species, average parasite density in microscopy positive cases
Study design	Were consecutive patients enrolled retrospectively or prospectively?
	Whether the sampling method was consecutive or random, or whether the method was not described but consecutive sampling was most probable
	If the study evaluated more than one RDT, how were tests allocated to individuals, or did each individual receive all the tests?
Target condition	Malaria parasitaemia
Reference standard	The reference standard test(s) used
	If microscopy was used, who performed it, and where?
	If microscopy was used, how many high power fields were looked at?
	If microscopy was used, how many observers or repeats were used?
	If microscopy was used, how were discrepancies between observers resolved?
Index tests	The parasite species the test was designed to detect, the commercial name, and the type of test. Batch numbers if provided. Transport and storage conditions. Details of the test operators, including any special training provided.

(*Continued*)

Notes	Source of funding.

Appendix 3. Data extraction and criteria for judgement: methodological quality

Quality Indicator	Notes
Was the spectrum of patients representative of the spectrum of patients who will receive the test in practice?	'Yes' if the inclusion criteria clearly stipulated people attending an ambulatory healthcare setting with symptoms of malaria, and the sampling method was consecutive or random. 'No' if the sample was unrepresentative of people with uncomplicated malaria in general (for example, if the majority of participants also had some other presenting health problem, such as pneumonia). Where a proportion of potential participants were excluded due to recent antimalarial use, well defined co-morbidities or pregnancy, the sample could be classed as representative, because these groups may also be excluded from testing as normal clinical practice, depending on local policy and practice. 'Unclear' if the source or characteristics of participants was not adequately described; or if the sampling method was not described.
Is the reference standard likely to correctly identify the target condition?	'Yes' if microscopy was undertaken by experienced microscopists with adequate laboratory facilities. Laboratory facilities were assumed to be adequate unless the study report indicated otherwise. Slides were viewed by at least two independent observers, either for all slides or for those where there were discordant results between the index and the reference test. At least 100 microscopic fields were viewed before declaring a slide negative. 'Yes' if reference standard was PCR. 'No' if microscopy was undertaken by insufficiently trained individuals, by one individual only, or in a situation with inadequate equipment, or if they viewed less than 100 microscopic fields before declaring negative. 'Unclear' if insufficient information was provided.
Is partial verification avoided?	'Yes' if all participants who received the index test also received the reference test. 'No' if not all the participants who received the index test also received the reference test. 'Unclear' if insufficient information was provided to assess this. If not all participants received the reference test, we reported how many did not.
Is differential verification avoided?	'Yes' if the same reference test was used regardless of the index test results. 'No' if different reference tests were used depending on the results

(*Continued*)

	of the index test. 'Unclear' if insufficient information was provided. If any participants received a different reference test, we reported the reasons stated for this, and how many participants were involved.
Is incorporation avoided? (the index test does not form part of the reference standard)	Should be 'Yes' for all studies, as the reference standard is defined in the inclusion criteria as microscopy or PCR.
Are the reference standard test results blinded?	'Yes' if the person undertaking the reference test did not know the results of the index tests, if the two tests were carried out in different places, or it was clear that the reference test was undertaken and the results recorded before the index test. 'No' if the same person performed both tests, or if the results of the index tests were known to the person undertaking the reference tests. 'Unclear' if insufficient information was provided.
Are the index test results blinded?	'Yes' if the person undertaking the index test did not know the results of the reference tests, or if the two tests were carried out in different places, or it was clear that the index test was undertaken and the results recorded before the reference test. 'No' if the same person performed both tests, or if the results of the index tests were known to the person undertaking the reference tests. 'Unclear' if insufficient information was provided.
Were uninterpretable results reported?	'Yes' if the paper stated whether there were any uninterpretable or invalid results, and how those were handled; for example whether they were repeated until a valid result was obtained, or excluded from the analysis. 'No' if the number of participants presented in the analysis did not match the number of participants originally enrolled in the study, and insufficient explanation was provided for any discrepancy. 'Unclear' if uninterpretable or invalid test results were not mentioned, but the number of participants presented in the analysis corresponded to the number of participants reported to be originally recruited into the study, or if insufficient information was given to permit this judgement; for example if the original number of participants recruited into the study was unclear. We reported how many results were uninterpretable (of the total) , and how these were handled in the analysis.
Were any withdrawals explained?	'Yes' if it was clear that no participants were excluded from the analysis (the number of participants originally enrolled was clearly stated, and corresponded to the number presented in the analysis) or if exclusions were adequately described. 'No' if there were participants missing or excluded from the analysis and there was no explanation given; usually where the number

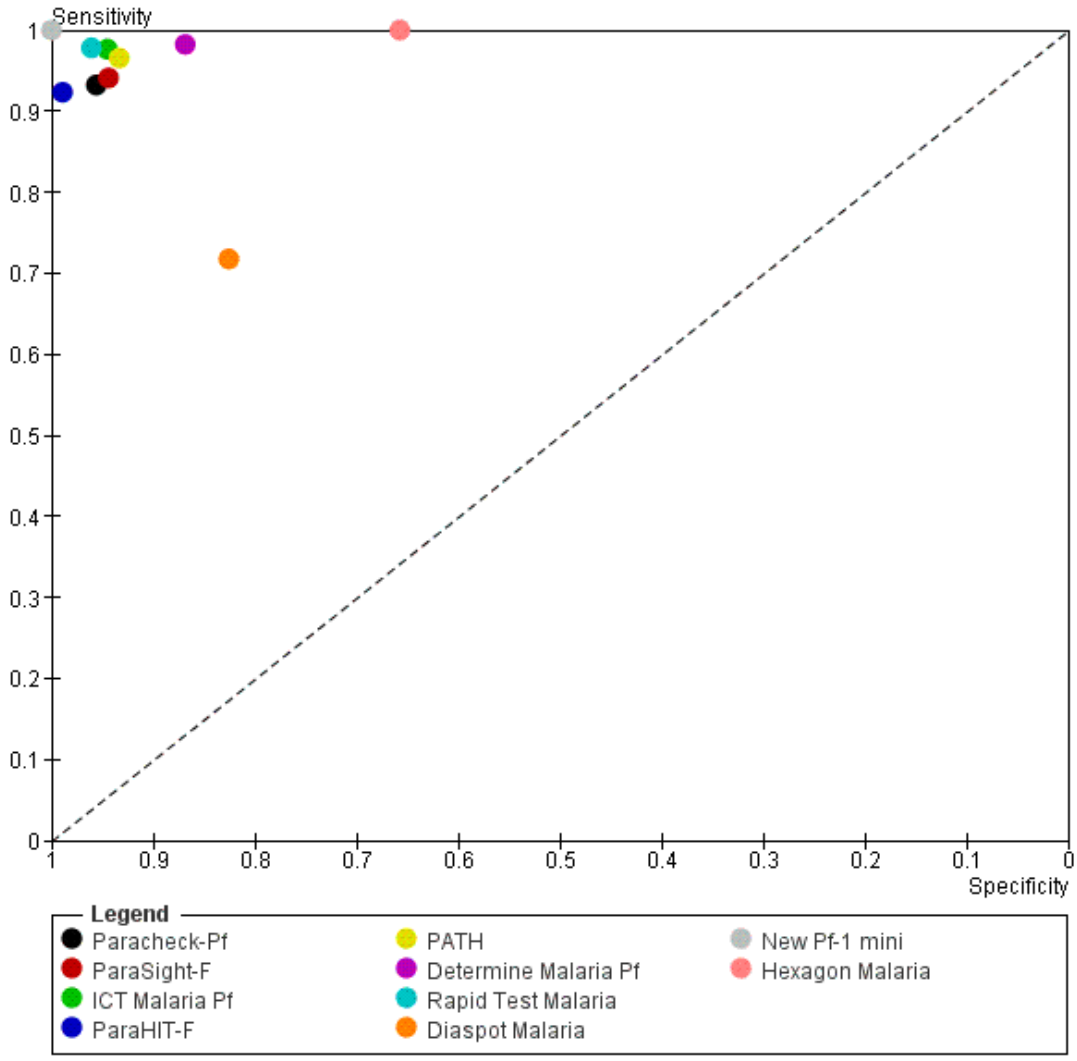
(*Continued*)

	of participants reported to have been enrolled and the number presented in the analysis did not correspond. 'Unclear' if not enough information was given to assess whether any participants were excluded from the analysis; for example if the original number of participants recruited into the study was unclear. We reported how many participants were excluded from the analysis.

Appendix 4. Extra figures

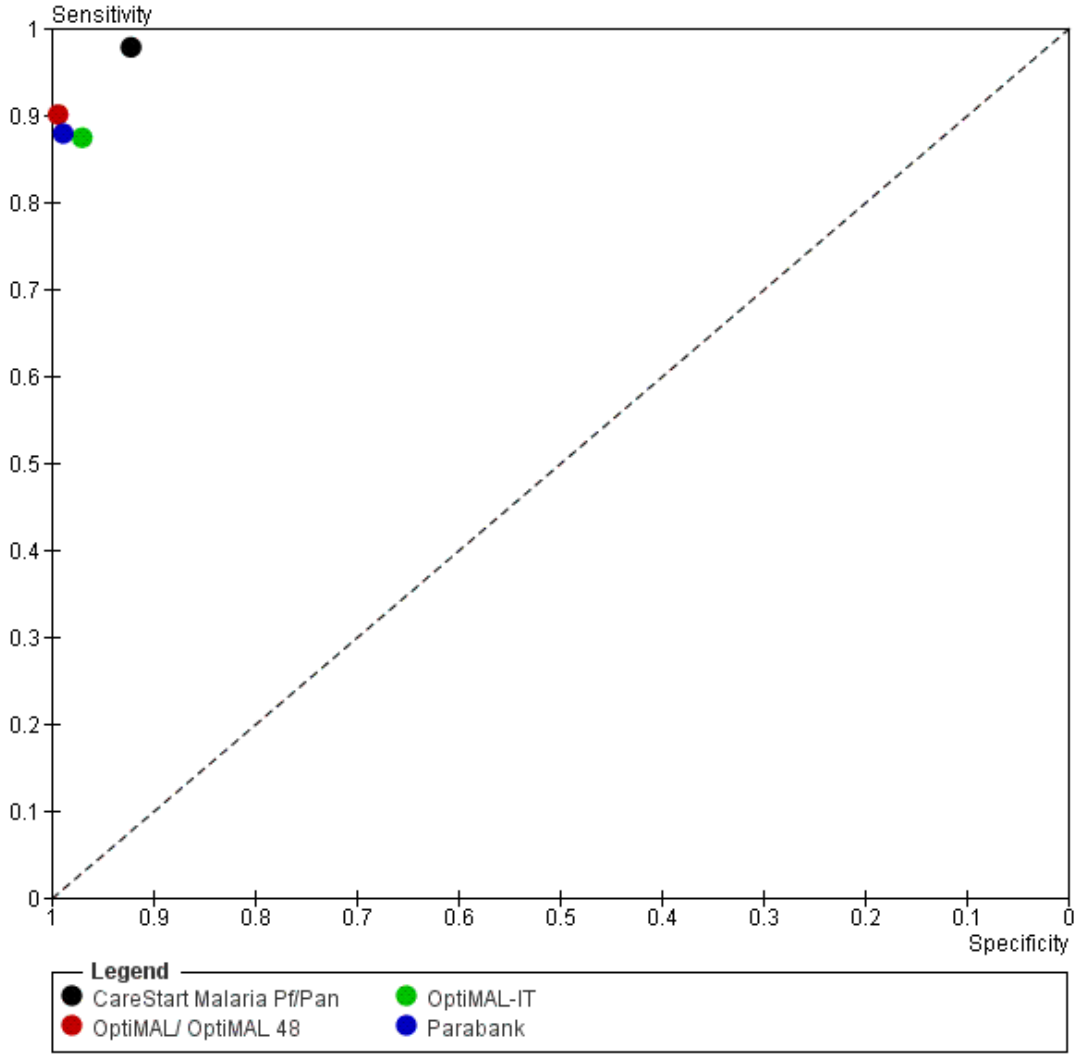
Estimates of average sensitivity and specificity for Type 1 RDT brands (Figure 8)

Figure 8. Summary estimates of Type 1 RDTs plotted in ROC space (by RDT brand)



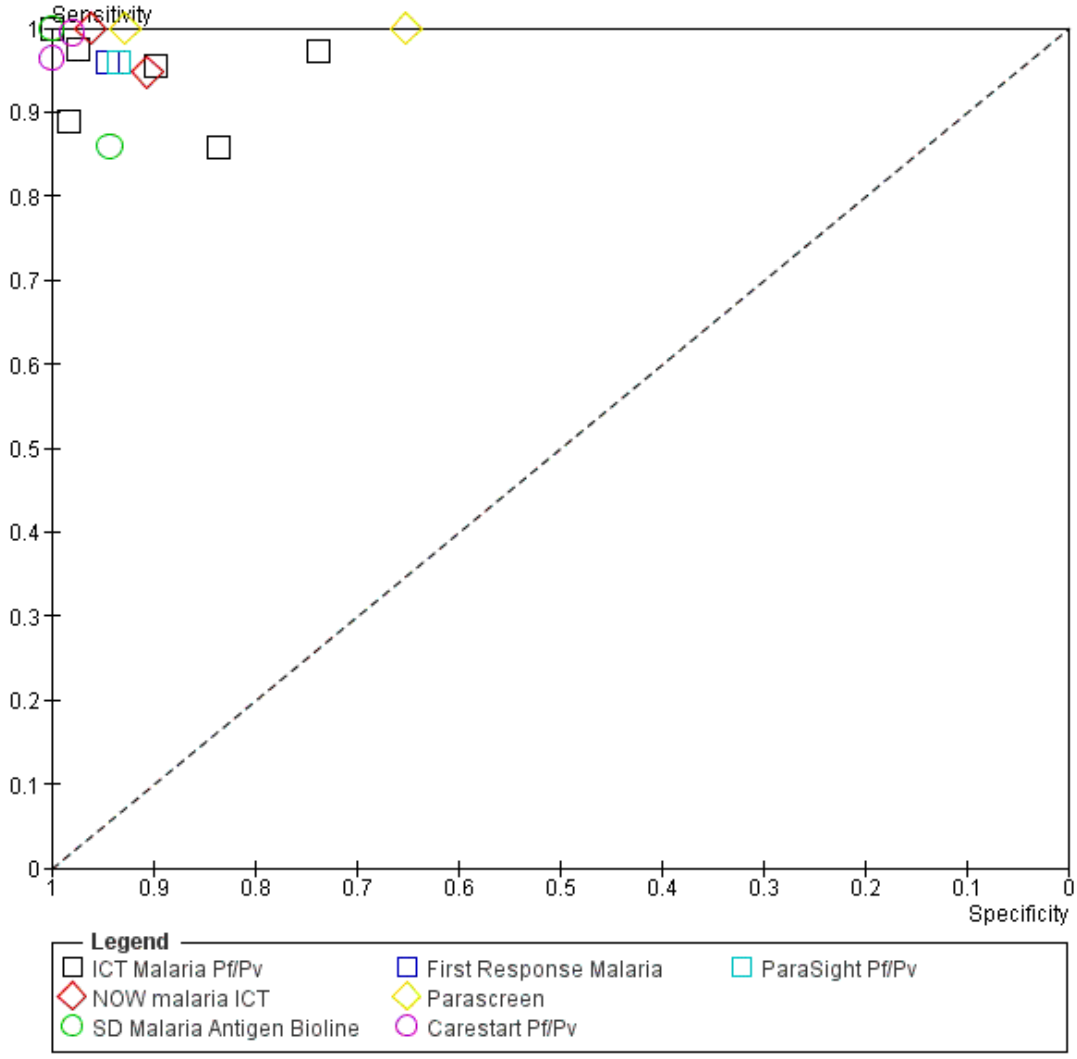
Estimates of average sensitivity and specificity for Type 4 RDT brands (Figure 9)

Figure 9. Summary estimates of Type 4 RDTs plotted in ROC space (by RDT brand)



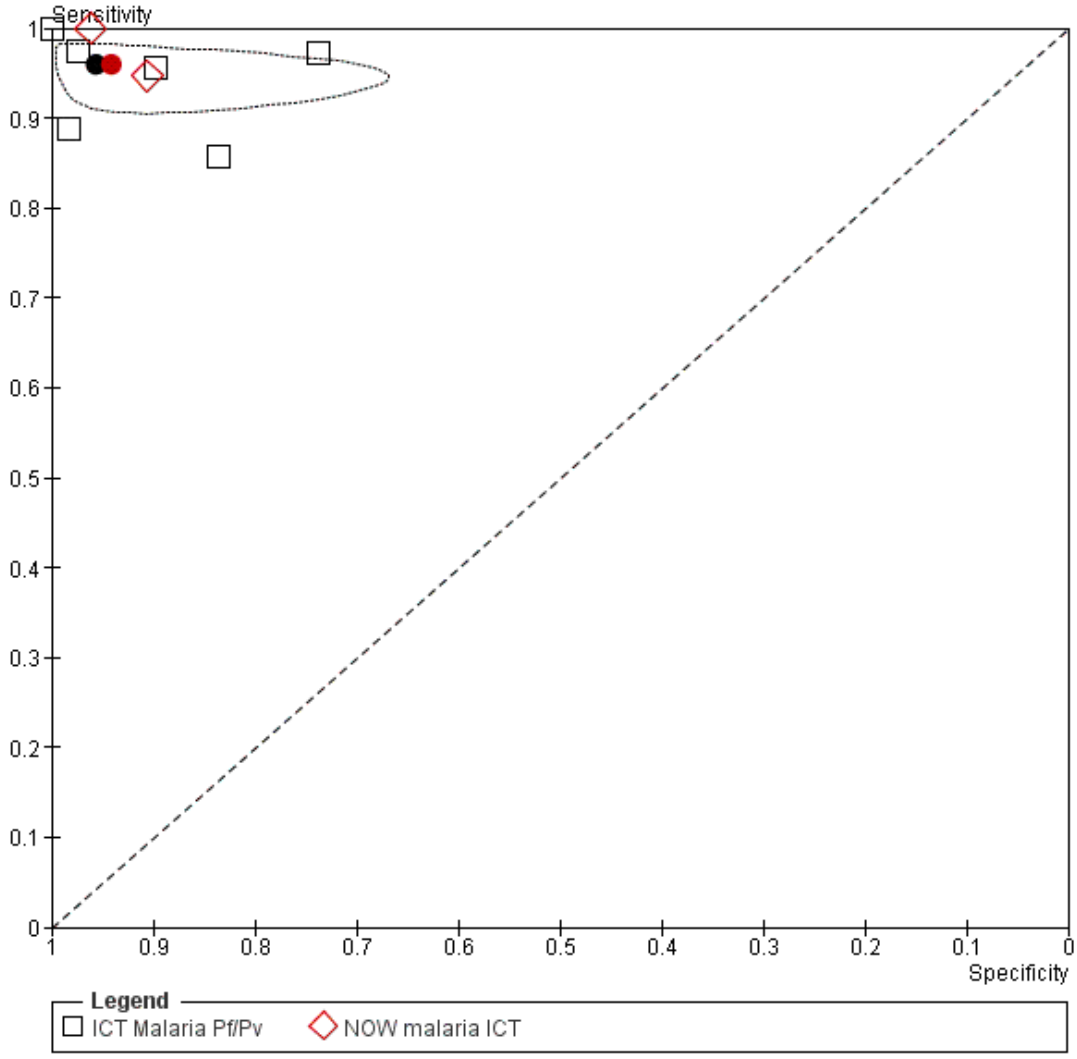
ROC plot of study results for Type 2, 3 and 5 RDT brands (Figure 10)

Figure 10. Study results of Type 2, 3 and 5 RDTs plotted in ROC space (by RDT brand)



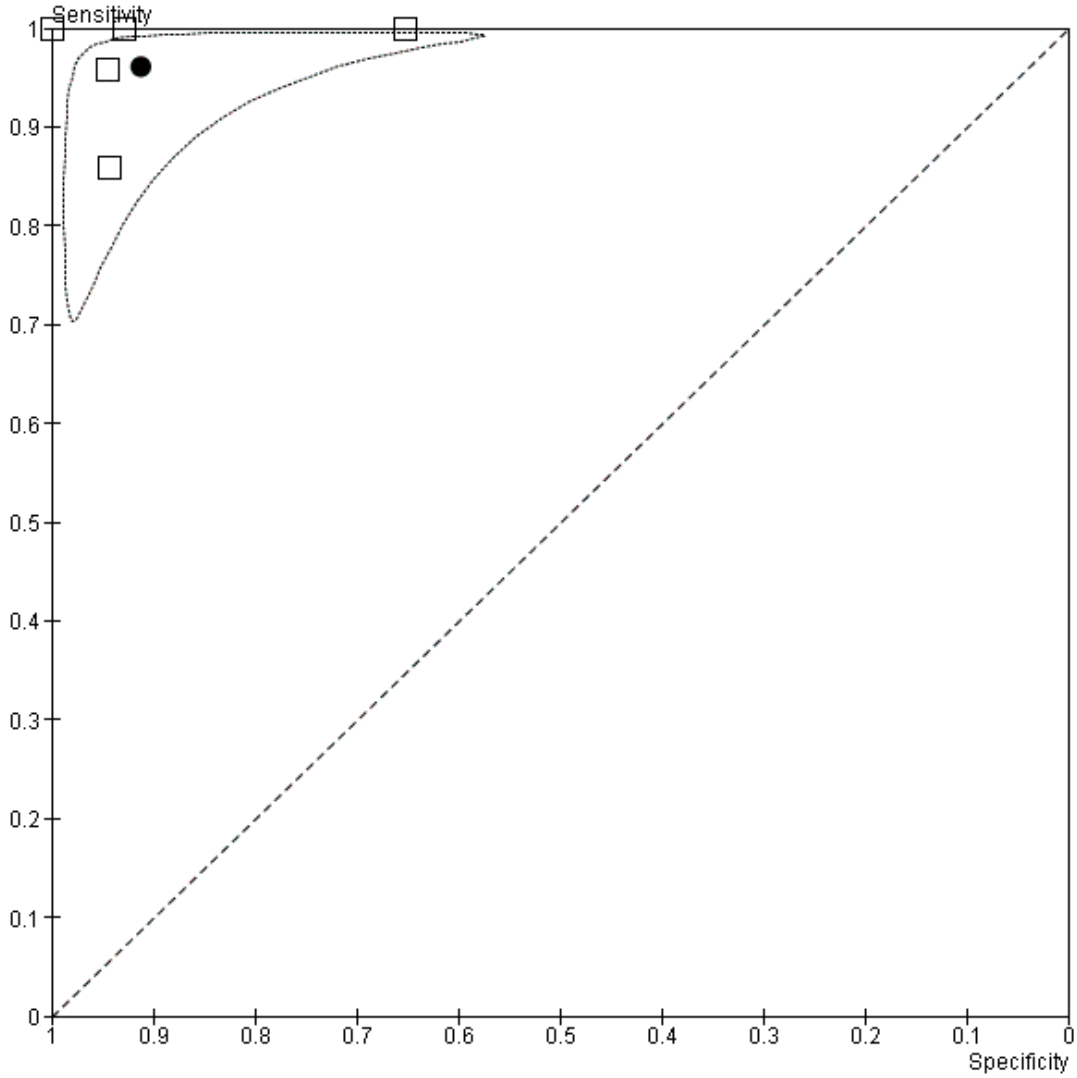
Study results and estimates of average sensitivity and specificity for Type 2 RDTs (Figure 11)

Figure 11. Summary estimates of Type 2 RDTs and study results plotted in ROC space (by RDT brand)



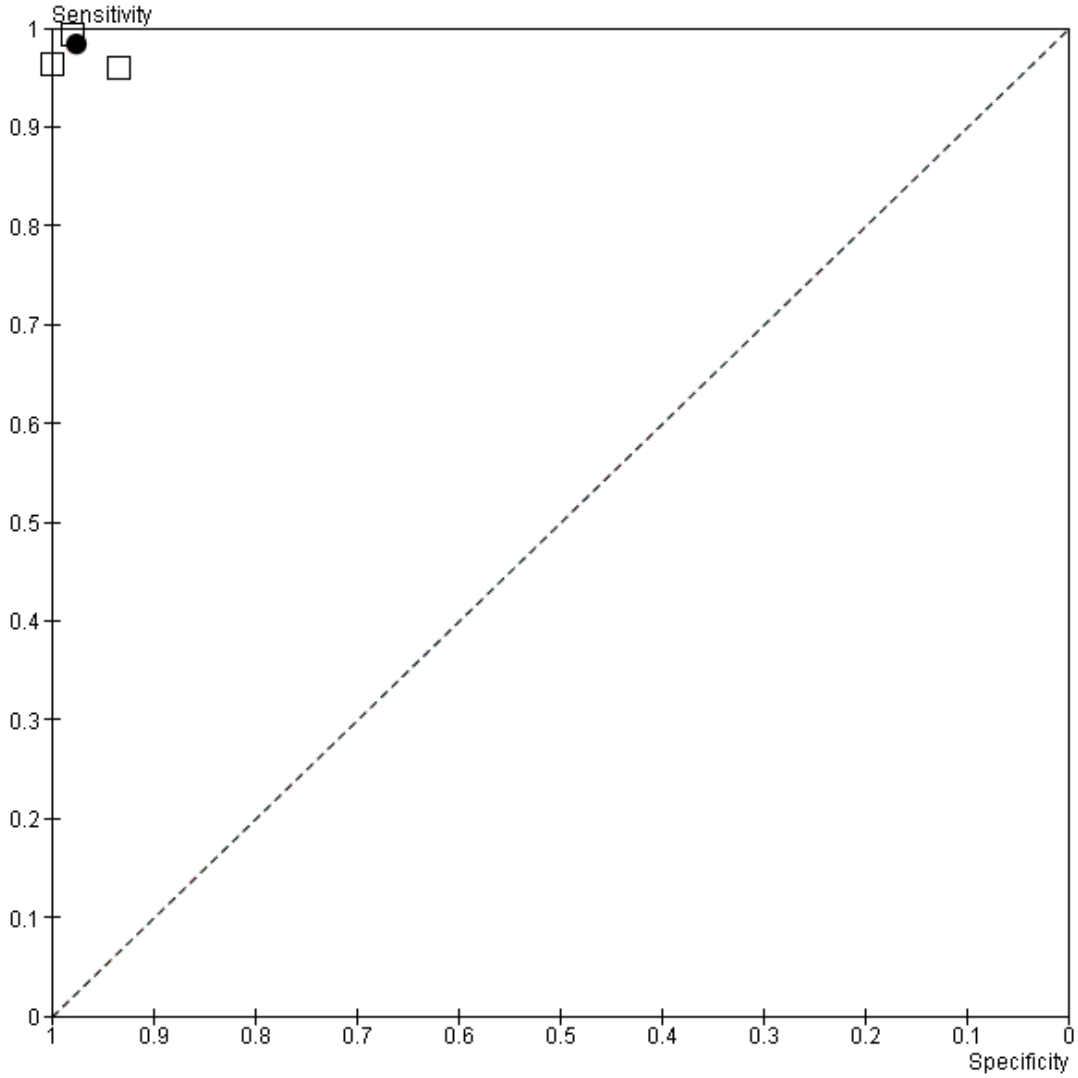
Study results and estimates of average sensitivity and specificity for Type 3 RDTs (Figure 12)

Figure 12. Summary estimates of Type 3 RDTs and study results plotted in ROC space



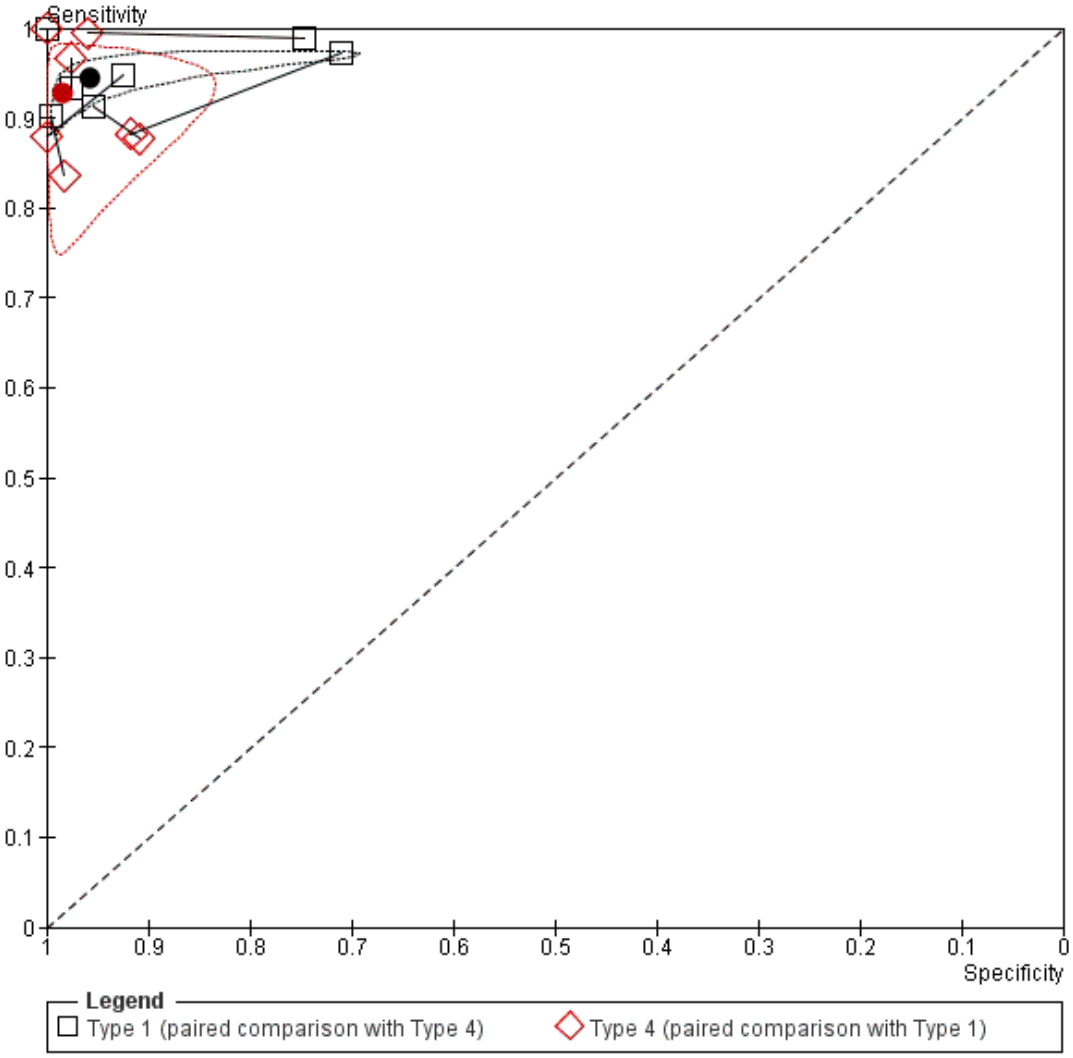
Study results and estimates of average sensitivity and specificity for Type 5 RDTs (Figure 13)

Figure 13. Summary estimates of Type 5 RDTs and study results plotted in ROC space



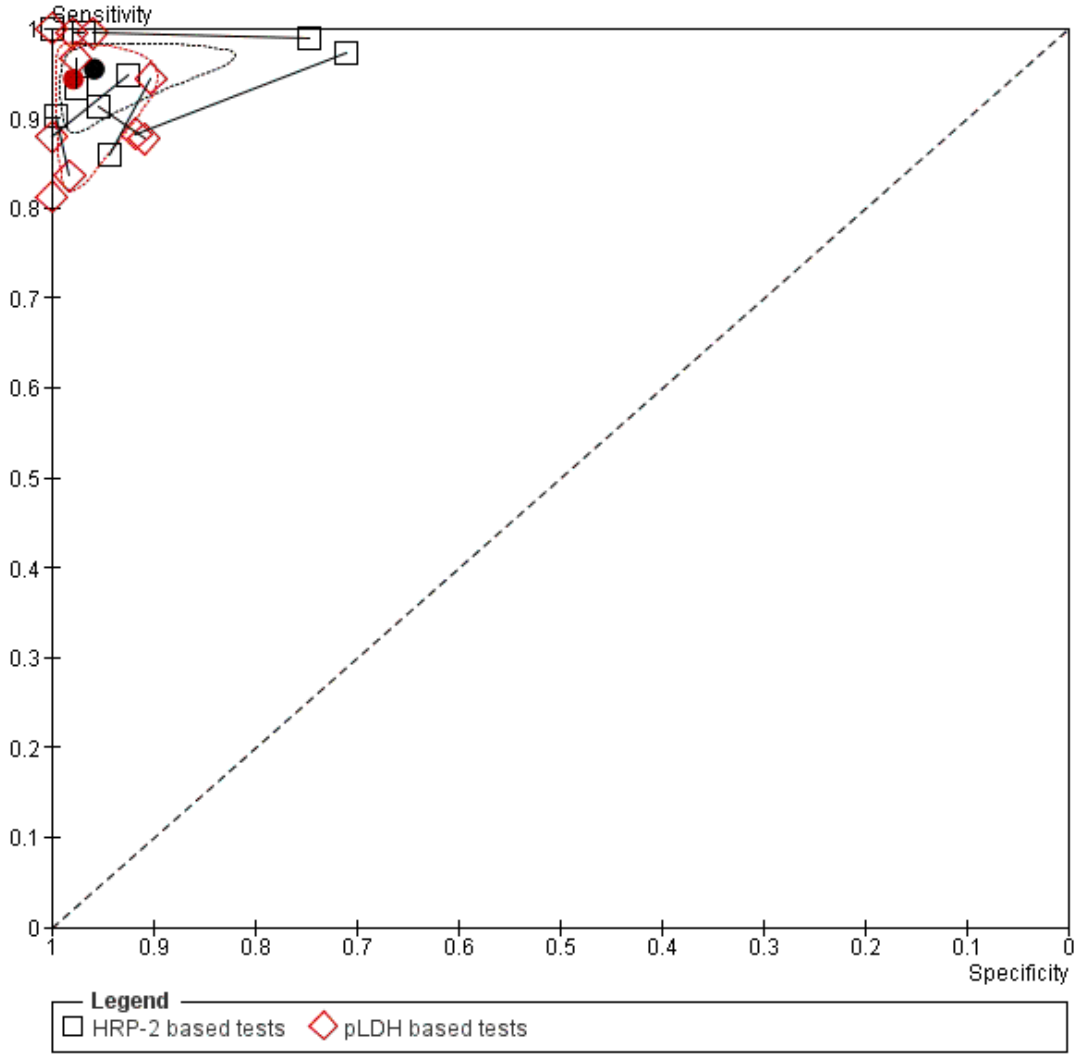
ROC plot of paired results which compare Type 1 and Type 4 RDT brands (Figure 14)

Figure 14. Paired comparison of Type 1 and Type 4 RDTs. Connecting lines link the direct comparison of pairs of tests in each study.



ROC plot of paired results which compare HRP-2-based tests and pLDH-based tests(Figure 15)

Figure 15. Paired comparison of HRP-2-based tests and pLDH-based tests. Connecting lines link the direct comparison of pairs of tests in each study.



Appendix 5. Type 1 RDT brands evaluated in more than 1000 participants

Ratio of sensitivity (95% CI) P value for comparison Ratio of specificity (95% CI) P value for compari			Paracheck-Pf	ParaSight-F	ICT Malaria-Pf
		Studies (participants)	27 (22,319)	17 (12,591)	16 (2955)
	Studies (participants)	**Sensitivity % (95% CI)** **Specificity % (95% CI)**	93.3 (89.7,95.7) 95.7 (92.7,97.5)	94.2 (89.8,96.8) 94.5 (90.3,96.9)	97.7 (95.5,98.8) 94.5 (90.4,97.0)
ParaSight-F	17 (12,591)	94.2 (90.1,96.7) 94.9 (91.0,97.1)	1.01 (0.96,1.06) P = 0.67 0.99 (0.95,1.03) P = 0.67	-	-
ICT Malaria-Pf	16 (2955)	97.7 (95.5,98.8) 94.7 (90.7,97.1)	1.05 (1.01,1.08) P = 0.01 0.99 (0.95,1.03) P = 0.63	1.04 (1.00,1.07) P = 0.05 1.00 (0.97,1.03) P = 0.93	-
ParaHIT-F	4 (1119)	92.6 (74.3,98.2) 98.9 (94.4,99.8)	0.99 (0.89,1.11) P = 0.89 1.03 (1.00,1.07), P = 0.03	0.98 (0.88,1.10) P = 0.76 1.04 (1.01,1.08) P = 0.02	0.95 (0.85,1.06) P = 0.33 1.04 (1.01,1.08) P = 0.02

Appendix 6. Additional direct comparisons between test types

	Sensitivity				**Specificity**			
	TP/diseased		**P value**	**change**	**TN/not diseased**		**P value**	**change**
Type 2 vs Type 1	**Type 2**	**Type 1**			**Type 2**	**Type 1**		
Van den Broek 2006	144/152	137/152	P = 0.19	+4.6% (-1.3% to +10.5%)	674/744	740/744	P < 0.001	-8.9% (-11.0% to -6.7%)
Type 2 vs Type 4	**Type 2**	**Type 4**			**Type 2**	**Type 4**		

(*Continued*)

Van den Broek 2006	144/152	127/152	P = 0.003	+11.1% (+4.3% to +18.1%)	674/744	731/744	P < 0.001	-7.7% (-10.0% to -5.4%)
Type 3 vs Type 1	**Type 3**	**Type 1**			**Type 3**	**Type 1**		
Mens 2007b	60/60	113/127	P = 0.006	+11.0% (+5.6% to +16.5%)	115/124	678/711	P = 0.26	-2.6% (-7.4% to +2.2%)
Dev 2004	17/17	21/21	P = 1.00	0% (not estimable)	13/13	9/9	P = 1.00	0% (not estimable)
Type 3 vs Type 4	**Type 3**	**Type 4**			**Type 3**	**Type 4**		
Mens 2007b	60/60	58/60	P = 0.50	+3.3% (-1.2% to +7.9%)	115/124	121/124	P = 0.14	-4.8% (-10.1% to +0.5%)
Dev 2004	17/17	69/85	P = 0.07	+18.8% (+10.5% to +27.1%)	13/13	54/54	P = 1.00	0% (not estimable)
Type 5 vs Type 1	**Type 5**	**Type 1**			**Type 5**	**Type 1**		
Sharew 2009	167/168	167/168	P = 1.00	0% (-1.6% to 1.6%)	490/500	484/500	P = 0.32	+1.2% (-0.8% to +3.2%)

Appendix 7. Summary of results by RDT type and reference standard

	Microscopy				**PCR**			
Type and RDT brand	**Number of studies**	**Number of patients**	**Pooled sensitivity (95% CI)**	**Pooled specificity (95% CI)**	**Number of studies**	**Number of patients**	**Sensitivity (95% CI)**	**Specificity (95% CI)**

(*Continued*)

Type 1, ParaSight-F	17	12,521	94.7 (92.0, 96.5)	94.6 (91.6, 96.6)	1	520	92 (86, 95)	99 (98, 100)
Type 1, ParaHIT-F	4	1119	97.0 (92.2, 98.9)	97.2 (92.2, 99.1)	1	336	72 (51, 88)	100 (99, 100)
Type 4, OptiMAL-IT	3	1356	87.4 (80.0, 92.4)	96.9 (88.4, 99.3)	1	313	73 (62, 81)	99 (97, 100)
Type 3, SD Malaria Antigen Bioline	2	224	Dev 2004: 100 (80, 100) Ratsimbasoa 2007: 86 (76, 93)	Dev 2004: 100 (75, 100) Ratsimbasoa 2007: 94 (89, 98)	1	198	94 (88, 98)	92 84, 96)
Type 6, PALUTOP	0	0	-	-	1	313	95 (88, 98)	97 (94, 99)

Appendix 8. Comparison of local microscopy and RDTs verified with good quality microscopy

Study	RDT	Local microscopy		RDT	
		Sensitivity	Specificity	Sensitivity	Specificity
Kolaczinski 2004	OptiMAL	85.2	99.7	79.3	99.7
De Oliveira 2009	Paracheck-Pf	52.5	77.0	91.7	96.7

WHAT'S NEW

Last assessed as up-to-date: 13 January 2010.

Date	Event	Description
6 July 2011	Amended	Plain language summary added.

HISTORY

Protocol first published: Issue 4, 2009

Review first published: Issue 7, 2011

CONTRIBUTIONS OF AUTHORS

The Cochrane Editorial Team identified this review as a priority topic for a Cochrane review. The protocol was developed jointly by the authors. Katharine Abba, Sally Jackson, and Cho-Min Naing applied inclusion criteria, extracted data and entered the data, with guidance from Paul Garner, Piero Olliaro, and Jon Deeks. Statistical analysis was carried out by Yemsi Takwoingi, Sarah Donegan and Jon Deeks. Katharine Abba wrote the first draft of the review. All authors contributed to the final manuscript.

DECLARATIONS OF INTEREST

There are no known conflicts of interest.

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External sources

- Department for International Development, UK.

Research Programme Grant

- NIHR Cochrane Diagnostic Test Accuracy Support Unit, Not specified.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

We intended to consider RDTs for detecting all species of malaria in a single review. We subsequently decided to split the review into two to make it more readable.

We had intended to handsearch reference lists of included articles, contact test manufacturers for any unpublished studies, handsearch conference proceedings, and contact authors and other experts for information on ongoing and unpublished studies. However, due to the number of citations returned by our search (over 4000), these activities were not required.

We added four further exclusion criteria: studies that used active case detection to recruit participants; studies that did not present absolute numbers; studies not published in English; and studies not presenting sufficient information to enable a full assessment of their eligibility.

NOTES

The CIDG editors responsible for editing this review were Dr Hasifa Bukirwa and Dr Hellen Gelband.